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ULCER KIT

Mimosa srl, with its own brand name Sanyleg, is leader in the production of Preventive and Medical Stockings. Italian elegance and style go hand in hand with the very best technologies for the well-being and health of legs. The articles of greatest interest for the market belong to the following 4 lines:

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Elastic Cotton Socks manufactured in 4 compression levels, suitable for anyone seeking for comfort and prevention.

Diabetic Socks for Sensitive Skin designed to avoid any inconvenience caused by rubbing and tightness. Recommended for diabetes sufferers or those with sensitive and delicate skins. Suitable for anyone that simply is seeking quality and comfort.

Therapeutic Stockings recommended by specialist doctors for the treatment of the most important venous pathologies: swollen legs, oedemas and varicose veins.



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HALL 5/L05

SANYLEG
EXCELLENCE MADE IN ITALY

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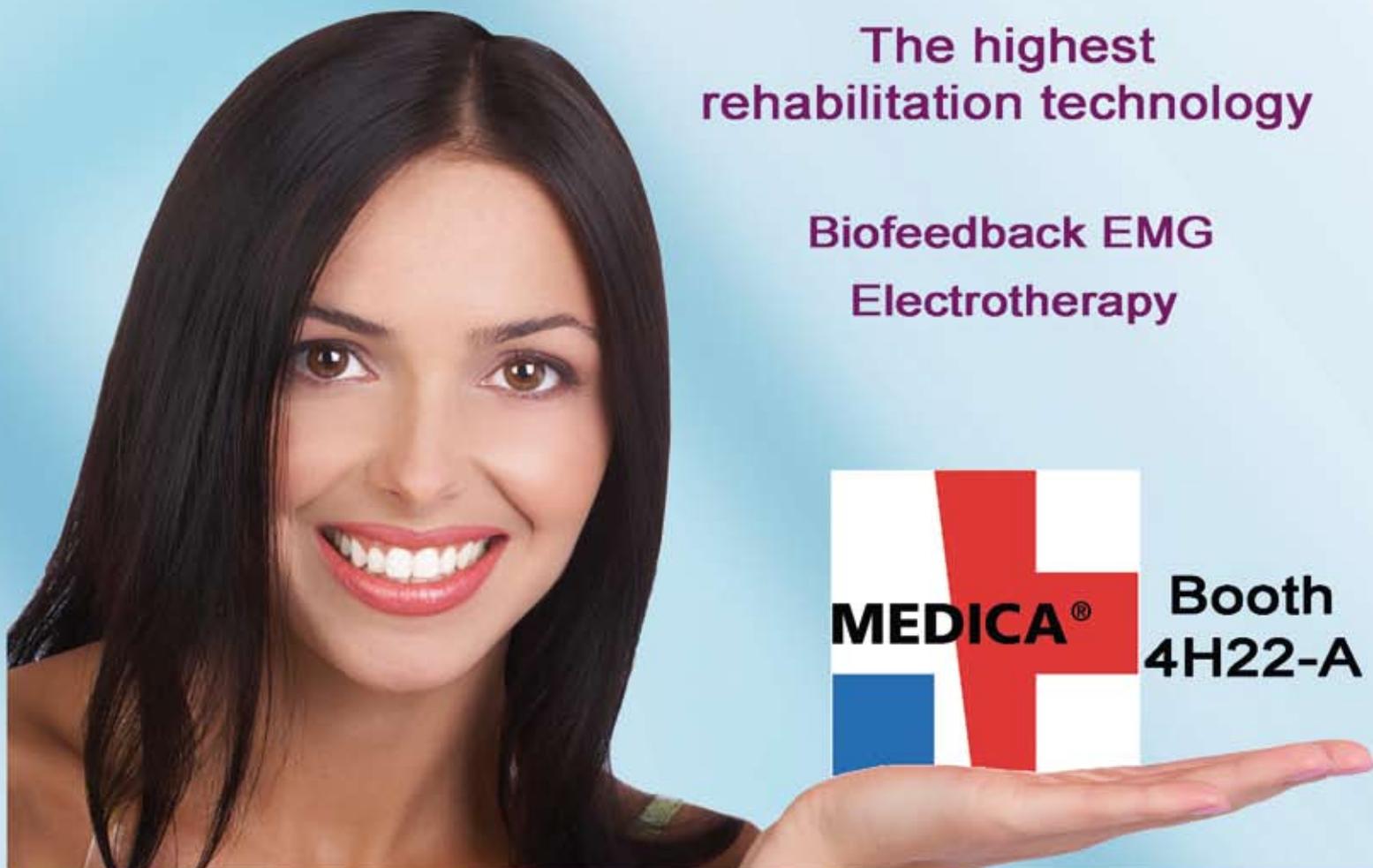
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Physiotherapist Teacher - Paris

"At last, a device which allies ergonomy and physiologically adapted protocols."

Guy Valancogne

Perineology Teacher - Lyon

"The technology and a team at your service matching your professional competence and proficiency."

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"At last a reliable Biofeedback..."

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SURGYSONIC MOTO: Moving forward.



Esacrom, is leader in the design and production of electronic and medical devices and is continuously working on the evolution in the field of hard tissue surgery.

The skilled experiences of Esacrom staff in terms of electronics and mechanics, together with the national and international expertise of our

scientific board, have set the basis for the realisation of a new device, which represents a turning point in hard tissues surgery.

SURGYSONIC MOTO, is a combination between the technologies of "Piezo" and "micromotor brushless". It confirms the brand Esacrom in the dental field and widens its application to the General Microsurgeries: Neurosurgery, ETL, Maxillo-facial and Orthopaedics.

Esacrom's evolution does not stop, but will continue for more and more to transform new ideas of today into the reality of tomorrow, finding new solutions again.

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New DocUReader 2

The new DocUReader 2 is a compact size urine analyzer designed to read and evaluate the Labstrip U11 Plus urine test strips. Continuing its predecessor's mission, the DocUReader 2 system is featured by simple operation, cost-efficiency and high quality while several significant improvements ensure enhanced performance and usability. Giving you the data management you need to efficiently perform for urinalysis testing the system provides advanced security, data recording and control features including QC reminders and lockout functionality.

The manufacturer 77 Elektronika is a Hungarian private company developing and manufacturing IVD medical devices, mainly urine analyzers, blood glucose

meters and their consumables. These products are supplied all over the world under 77 Elektronika's own brand name, as well as OEM and ODM products for market-leading multinational companies in the field of medical electronics.

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Algorkorea

Algorkorea manufactures various types of brand new 2~32 channel digital hearing aid CIC/ITC/ITE/MiniBTE/BTE models as well as bone conduction spectacles, neck laced type, wireless FM model. Our customized models are manufactured with the 3D rapid production process. Many models are ISO 9001, ISO 13485, CE, sFDA, GMP qualification certified for overseas supply.

Our Clear 8 channel CIC model guarantees 100% DSP performance and comfortable sound quality with tinnitus treatment, real-time 128 band graphic equalizer, auto adaptive directivity, auto adaptive feedback cancellation, auto adaptive noise reduction, real-time in-situ, data Log functions.

We are further developing next generation sophisticated hearing aids with speech recognition features for profound or deaf hearing impairments. Hearing aid is not just for listening, but also for seeing.

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Atlas Specialty Lighting



Atlas Specialty Lighting provides quality brand-name medical bulbs and biomedical batteries for any and all applications at competitive prices, with an excellent customer service. Our experience staff is always prepared to assist in identifying the correct product for any needs.

Our product is the high quality for the medical sector. We distribute over 32,000 products from over 145 manufactures and we ship anywhere in the world from our different stocking locations across the United States.

Atlas Specialty Lighting is one of the largest stocking distributors of replacement lamps and biomedical batteries for the medical industry in the country for all types of medical equipment including: Microscopes, Operation Room Lamps, Fiber optic, Endoscopes, Bio-Medical Equipment, Projectors and others.

Lamps and Batteries are available for equipment from: Perkin Elmer ~ Welch Allyn ~ Olympus ~ Fujinon ~ Pentax ~ Nikon ~Leitz ~ Storz ~ Stryker~ Baxter ~ Wolf ~ and much more! Lamps can also be made to order if needed in many cases. ATLAS stocks Cermax Xenon cold light source replacement lamps for most medical, surgical, and Endoscopic use.

For more information visit our Website: www.asltg.com

Cross Healthcare Ltd

We are a UK licensed pharmaceutical distributor. We can locate branded pharmaceuticals, generic, OTCs, Toiletries, Medical, Surgical and other Healthcare products worldwide. With offices across Europe, we have the ability to analyse many markets and provide your company with the products you desire

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Model RCT-500+S, Digital Micro Centrifuge

Designed for safe centrifugation of small quantity of samples. The unit made with metal housing for easy maintenance. LED digital display enables users to monitor the present speed value and remaining time. Timer can be set from 0 to 30 minutes and buzzer at the end of operation. Rubber feet and auto balancing for high stability which could avoid vibrations transmission. Adopting high quality motor with good ventilation system to prevent the motor from overheating. This unit is equipped with safety lid lock, lid is closed during operation.

Specifications: Digital micro centrifuge. Main construction: Powder coated steel, SS304, ABS and base with 4 rubber feet, Motor: Noiseless powerful DC motor, Speed: 500~4,000rpm adjustable, Speed display: LED display, Max. R.C.F (G-force): 2,735, Timer: 0~30min adjustable, Manual brake: yes, Rotor type: Swing out, Number of tubes: 16 / 12 / 4pcs, Tube size: 5~7 / 10~15 / 50ml, Tube holder size: 7 / 15 / 50ml



REXMED www.rexmed.eu

MEDICAL COMPRESSORS

The basis of Ekom s.r.o. production is formed by oil-less dental compressors, dental suction units and relevant accessories for application in dental surgeries, laboratories and central compressed air systems, as well as by medical compressors serving for supplying lung ventilation equipment with medical compressed air.

The connection to central air distribution through WALL inlet is optional. The idea of launching "EASY" medical compressor line is obvious – to make medical grade air compressor line more affordable and attainable for limited cost projects as well as project where comfort and utility of DK50 DS compressor version is not required.

Along with high-end level medical compressors Ekom s.r.o. introduces simplified versions of DK50 DS compressor range under the designation DK50 DE. "EASY" medical compressor line is equipped with all necessary features to provide lung ventilation devices with requested compressed medical grade air. Simple metal case covers the same compressor air pump used in DK50 DS line, yet the construction contains no alarm, one OUT outlet, mechanical air gauge and operation hour counter as standard features.

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SURGYSONIC MOTO and T-BLACK: Moving forward.



Esacrom, is leader in the design and production of electronic and medical devices and is continuously working on the evolution in the field of hard tissue surgery.

A brand new finishing is applied on our standard tips resulting in a more effective cut and lower heating of the tissue. At the same time thanks to the higher hardening we can grant a less abrasion and wear out and the anti reflective surface grant a better visibility of the operating fields.

The skilled experiences of Esacrom staff in terms of electronics and mechanics, together with the national and international expertise of our scientific board, have set the basis for the realisation of a new device, which represents a turning point in hard tissues surgery.

The whole range of our "tips" are made by our own production facility and represents the largest number of models present in the market. Esacrom pays very much attention to details. In fact the new concept is the result of a long and continuous research of Esacrom, translated in its current design by Sardi Innovation – leader in the Innovation business. Surgysonic moto will be available in different colours to satisfy different aesthetic needs and the very compact configuration has been designed to allow an easy handling and need a minimum of space in the clinic.

SURGYSONIC MOTO, is a combination between the technologies of "Piezo" and "micromotor". It confirms the brand Esacrom in the dental field and widens its application to the General Microsurgeries: Neurosurgery, ETL, Maxillo-facial and Orthopaedics. And Ultrasonic Wound Debridement. ESACROM regularly invests time and resources in the development of new products and new finishing.

Other innovative solutions are still in-progress and soon will become true, thanks to the skills and energy of Esacrom's team and the investments in research and development. Esacrom's evolution does not stop, but will continue for more and more to transform new ideas of today into the reality of tomorrow, finding new solutions again.

To this purposes we would like to introduce the new line of T-Black.

ESACROM SRL
www.esacrom.com
Esacrom@esacrom.com

Hogies Australia will be releasing a world first product at Medica 2010

The Hogies MaxiLux is a remote control LED Light with a rechargeable power source, two brightness settings and true coaxial alignment. With 15,000 Lux of Illumination and 12 hours battery time the MaxiLux offers a fully compatible for all types of magnification systems. The products are made in Australia.

For more information visit:
www.hogies.com



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myESR.org/registration2011

Vienna
March 3-7



AMODinsù – Three different compressions in one pantyhose



MODinsù is a real innovation in the stockings market. With its panty, made in different connected compressions, it supports, shapes and keeps fit your glutei and your hips, while its graduated compression (electronic) produces a beneficial massage on your legs, making them beautiful, slim and nimble.

message on your legs, making them beautiful, slim and nimble.

The simple everyday habit of wearing a pair of MODinsù stockings will be the fastest and easiest way for supporting your glutei. The panty has three different compressions: strong and sustaining under the glutei, where control is mostly needed; light on the lower abdomen where compression is not required; strong and sustaining in the hips and around the waist, where cellulites and fats accumulation can easily form. This products quality is self-explained by six features: graduated compression, double layer Lycra® weaving, reinforced and well-shaped heel and toes, elastic band knitted around the waist, anatomic wedge and extra flat seams.

For more information visit www.farmasystemsrl.com
VISIT US AT MEDICA: HALL 4 / D 31

MODULAR AND VERSATILE SYSTEM FOR PRIVACY SOLUTION



LM Medical Division is a manufacturer of medical equipment and furniture.

After 15 years experience in manufacturing of electro medical equipment, LM Medical Division is developing with

a new products and new qualified working team.

The new line is a modular and versatile system with telescopic rods and fixed screens with curtains; offers a simple and effective solution to ensure the patient's privacy.

The line is the result of the great professionalism and quality getting in 15 year experience working in the medical field.

The products is 100% made in Italy and top level quality: the adjustable telescopic is in anodized aluminum; the joint parts and wall support are in nylon; the fabric is 100% Trevira CS. The complete products is flame-retardant and anti bacterial.

The models, thanks to their versatility, can be fixed to the wall or ceiling in response to every needs. The system includes a trolley on wheels model for emergency situations.

The modern and nice design and the refinement of the fabrics gives the best solution for integration and decoration for all environments.

More info on : www.lmmmedicaldivision.eu - sales@lmmmedicaldivision.eu

Next Generation, New Innovation Skin Renewal system



Arneb™—Treatment of Fine Lines, Wrinkles and Skin Laxity

Predictable and virtually pain-free, the Arneb™ skin renewal system with Electro-Optical-Photo pneumatic combines synchronized synergy therapy. EOpX™ technology is a revolutionary approach to skin tightening and the treatment of wrinkles.

During treatment with this novel technology, an integrated vacuum gently draws the skin into the treatment tip, where it receives a controlled bipolar pulse of radio frequency (RF) energy. The energy is deposited deep in the dermis denaturing collagen without injuring the epidermis or causing pain.

This starts a natural healing process that brings about collagenesis and eventually wrinkle reduction.

Arneb™ Thermal Fine Lift is EOpX™ Technology

The innovative technology EOpX™ (Electro-Optical-Photo pneumatic combine synchronized synergy therapy) introduces the new generation for the skin tightening and the reduces of wrinkles into the recent market for the leading dermatologists. This state-of-the-art technology, Electro-Optical-Photo pneumatic, combines synchronized synergy therapy.

EOpX™ features that the hand-piece tip pinches the skin up softly by the gently generated vacuum.

EOpX™ delivers the controlled bi-polar radio frequency (RF) energy and the high-powered dual diode lasers energy simultaneously deep into the dermis painlessly which enhance the collagen production in the dermis without any damage to the epidermis.

For detailed information, visit www.medro.net

OLSEN

One of the largest dental & medical equipments manufacturers in Latin America, Olsen is the winner of countless national and international awards. Certified by ISO 9001 and CE marking, Olsen's quality is recognized in Brazil and worldwide.

The company exports to over a hundred countries and the state of art of four products is the main reason for the prestige. With innovative design, high durability and low maintenance cost, Olsen detaches itself among the best professionals since 1978. With a new concept in medical equipment Olsen has developed examination tables for excellence on the job and all the

comfort needed for the patient. When a doctor purchases our equipment, he knows he is taking the result of an intensive investment in development, research and technology. Meet now the results of all Olsen's work and take world class equipment to your office.

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ETTORE JACKET



Latino has been making professional sanitary clothing since 1991 producing garments both stylish and functional, using 100% mercerised and sanforised cotton, Indanthren dyed and according to UNI EN ISO standards. One of our strengths is represented by the fact that every product is manufactured with natural fabrics only and is strictly Made in Italy. A fundamental concept for Latino's is that of never having to renounce to the elegance, also in the working environment. This is the reason why Latino professional line highlights all the reliability, the refinement, and the style

of the professional, by creating garments perfect for such a role, beautiful and extremely fashionable at first sight, and at the same time practical and comfortable. Latino latest collection, in particular, is characterized by a high fashion-content component, given by colours following the market trends. In fact, the range of basic colours keeps on being enriched, with the introduction of new shades based on the popular colours of the season or according to specific market requests (for ex. the introduction of black colour to this latest collection).

LATINO – Italy
 Tel: +39 049 9450820 - Fax: +39 049 5996820
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ECHONOX®

ECHONOX® is the echo reflecting metal alloy offered by STERYLAB for its range of special procedure needles.

ECHONOX® provides an optimised visualization of the whole needle under ultrasound guided biopsy procedures. By the nature of its constituent material it functions at any angle of entry into the body in relationship to the generation of sound waves by the ultrasound transducer. Thanks to its perfect smoothness, avoids any risk of seeding of malignant cells along the needle's path from the patient's body out.

ECHONOX® alloy is designed to enhance the visibility of the whole needle during an ultrasound guided needle biopsy, localization, or any access pro-

cedure. ECHONOX® allows visualization of the whole needle without impeding the smooth passage of the needle through the surrounding tissue.

The function of this special material is independent of the angle of entry of the needle into the tissue, as it relates to the sound waves generated by the ultrasound transducer. The material works as well as shallow angles of entry as well as near vertical angles.

For more information visit:
www.sterylab.it



Aurelia® The extraordinary examination gloves



Aurelia® Refresh™ – Mint scented glove

Be sure to try „The Dentist Favorite Glove“ combined with unique green peppermint scent and patented honey comb™ texture latex examination glove. The gloves provide the sheer feel of all-natural sensation with extraordinarily refreshing touch by providing a new dimension of

comfort. Also available as non scented but white glove with honey comb™ texture (Aurelia® Distinct™).

Aurelia® Protégé™ – Stretch nitrile glove

Aurelia® Protégé™ stretch nitrile examination gloves meet the comfort and fit of latex without the worry of latex allergic reaction. Manufactured with „Smart Technology“ makes it so stretchy and lightweight like a second skin but still providing durability and comfort. The finger texture improves tactile sensitivity and non-slip grip.

SUPERMAX Deutschland GmbH – Germany
 Tel: +49 2336 470520
 E-Mail: mail@supermax-gmbh.eu
 Websites: www.supermax-gmbh.eu/www.aureliagloves.com

REHABILITATION: BIOFEEDBACK & ELECTROTHERAPY

YSY MEDICAL is a French manufacturer specialized in rehabilitation by biofeedback, EMG muscular evaluation and assessment, electrotherapy and ultrasono-therapy.



We offer a range of products with unique features: undisturbed EMG biofeedback signal, true real time biofeedback (without latency), high EMG sampling allowing accurate unparallelled acquisition, effective and very comfortable stimulation, wireless technology...

All treatment protocols are designed in partnership with leading international trainers. Applications for therapy: urogynecology, men urology, proctology, sport, central and peripheral neurology, traumatology, rheumatology, hemiplegia, vascular, aesthetics... The diagnosis before therapy is also possible: detection of denerved muscle, qualitative EMG, uroflowmetry, skin resistance measurement...

Devices come in two ranges: stand-alone and computerized systems. Certifications: ISO 9001:2008, ISO 13485:2003, CE mark 0120 by SGS

YSY MEDICAL - FRANCE
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Podotech Elftman Foot Pressure Platform

The Podotech Elftman Foot Pressure Platform utilises state of the art pressure mat technology and electronic sensors to provide extensive analysis options. 3 scan types - static, dynamic and postural; enabling patients to be scanned whilst standing, walking or running. Superior visual analysis is provided via 3D scans, graphs and reports that encourage patient interaction and facilitate a more accurate assessment.

Why choose the Podotech Elftman?

- Captures 100 images per second
- Sensor life time of over 1 million uses

- Thin pressure mat encourages natural gait
- Highly durable, permanent mat surface
- CE certification provides quality assurance
- No product calibration required
- Highly reliable and portable system



See it at MEDICA 2010: Hall 16 Stand G04-5

Contact us for further information and to request a product brochure
Podotech - UK

Tel: +44 (0) 151 448 1228

Fax: +44 (0) 151 448 1008

Email: sales@algeos.com

Website: www.Podotech.com

The Altera A.S.



Altera A.S. is a company operating in the Health Care sector located in Izmir, Turkey. Altera achieves production and assembling of the Disposable Medical Consumables with Altech brand manufacturing in 3 clean rooms (10,000 and 100,000 class).

The products are CE (certified by TUV Rheinland) and FDA marked and comply with ISO

9001, ISO 13485:2003 quality regulations. Altera A.S. also has a certification for ISO 14001 to show her sensitivity to environment.

Currently, Altera is making OEM supply & contract manufacturing to worldwide brands. Altera products are presented in 56 different countries worldwide. Our major product groups are:

Altech Breathing Systems

- 1- Breathing Circuits (Anesthesia Circuits, Ventilation Circuits, Heated Wire Circuits, CPAP/BPAP circuits, IPPB Circuits, Coaxial Circuits, Neonatal Circuits, Masks, Gas Sampling Lines, Breathing Bags)
- 2- Breathing Filters (Bacteria Filters, HME Filters, Bacteria/HME Filters, Tracheostomy Filters, Neonatal HME Filters)
- 3-Oxygen and Aerosol Therapy Products (Oxygen masks, Aerosol Masks, Nebulizers, High Concentration Re-Breathing Masks)

You may find more information from www.altera.com.tr

Mammography Unit

New mammography "MAMMO-R" unit will improve detection of breast cancer and improve the comfort of patients undergoing a mammogram. As part of a refurbishment to the unit a dedicated waiting and changing area has been developed providing space and privacy for patients.



Improved diagnosis and detection ultimately improves the prognosis for many with breast disease leading to a reduction in mortality:

- Compact and ergonomic system design
- Motorized C-arm height and rotation adjustment
- Touch-screen interface at assistant workstation
- Digital indication of breast compression force, compressed thickness and projection angle

In 2011 the new digital mammography equipment will be at You service. Uses digital technology enabling images to be viewed immediately in DICOM 3.0 standart.

AMICO JSC – Russia

Tel: +7 495 742 41 60

Fax: +7 495 742 94 14

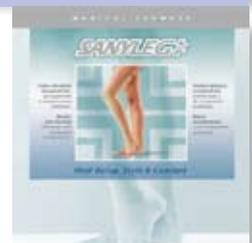
E-mail: export@amico.ru

Website: www.amico.ru

ETherapeutic stockings - Class II

These garments are manufactured using the new generation of high-elastic yarns, to reach high compression levels without spoiling the comfort and wearability.

Available in three different models: AD, AG, AT. They are recommended for the treatment of serious venous pathologies. These garments are strictly for medical use and must be prescribed by medical specialists.



For more information visit www.sanyleg.com

Certifier FA Plus ventilator test system

TSI, a worldwide leader in gas flow measurement technology, introduces the Certifier FA Plus ventilator test system. The Certifier FA Plus supports adult, pediatric, anesthesia, neonatal and high frequency ventilators.

The Certifier FA Plus includes a color touch screen user interface that can display up to eighteen parameters and a graph mode for flow and pressure. All software is embedded in the instrument with print and data storage of 1MB internally or 1GB on the SD flash card. Data can be downloaded to a computer via USB interface to create test reports and graphs of flow and pressure.

All standard ventilator test parameters are included in the instrument with gas calibrations for air, oxygen, air/oxygen mixture, nitrogen, carbon dioxide,

plus nitrous oxide with the optional low flow module. The Certifier FA Plus is the most affordable high performance ventilator tester on the market. Complete specifications are listed on www.tsi.com.

For detailed information, contact:

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Cressex Business Park

High Wycombe, Buckinghamshire

HP12 3RT United Kingdom

Telephone: +44 (0) 149 4 459200

Fax: +44 (0) 149 4 459700

E-mail: answersEU@tsi.com



GPC Medical Limited



GPC Medical Limited, the best name in India in its field, is ISO 9001 & ISO 13485 certified, WHO-GMP compliant with a large number of CE Marked products. Orthopaedic Implants/Instruments and Hospital Furniture are the two most specialized product ranges. GPC is perhaps the first and the only Indian company whose bone plates and bone

screws are US FDA 510(k) approved. The other products, exported regularly in large quantities, against international bids also, include Anaesthesia Products, S.S.Hospital Holloware & Sterilizers, Autoclaves, Suction Units, Shadowless Lamps, Diagnostic Instruments, Weighing Balances, Microscopes, Cold Chain Equipment etc. The customer satisfaction at GPC, is achieved by supplying quality products at low prices within a short delivery time, paying due attention to packaging and packing. There is hardly a country where the GPC products have not found their way. Many importers, particularly in European countries, even re-export the GPC products profitably.

For more information, please visit www.gpcmedical.com

Be part of the experience: Telemonitoring system "hLine" finally launched



Health telemonitoring on a new level – that's what the hLine promises to customers, doctors and patients. The whole system is centered around an innovative concept which will make it easier for healthcare professionals to collect and manage vital data. Besides many different measuring systems like blood glucose and blood pressure

monitors, fitness articles and scales, the hLine also offers data collection units that gather data from these monitors wirelessly. One of these units is the hFon – the world's first Telehealth smartphone with integrated blood glucose monitor.

With the help of this phone, vital data from all other meters can be managed in an easy and innovative way. The whole system can be individually adjusted to patient's and HCP's needs and it can also be integrated into other telemedicine systems. As an open telemonitoring infrastructure, the hLine will make it easier for end users, hospitals or telemedicine service providers to collect, manage and analyze measurement values.

HMM Group, the German-based manufacturer of this product line, is specialized in finding innovative solutions in the field of diagnostics. The product portfolio also includes a wide range of medical, fitness and wellness products.

Find out more about smartLAB® products and take a look at the innovative hLine concept: www.smartlab.org / www.hLine.eu.

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CMEF AUTUMN 2010 - 64th China International Medical Equipment Fair



With the approval of the MINISTRY OF COMMERCE, PRC, the 64th China International Medical Equipment Fair (CMEF) will be held on October 12-15, 2010 at Shenyang Exhibition Center in Shenyang.

This fair covers an area of 110,000 SQM, 5200 booths and over 2000 exhibitors. The main exhibition hall is categorized by products and divided into exhibition areas of CMEF Imaging, Medical Electronics, Medical Optics, Surgical Equipment

and Emergency Medicine, Hospital Equipment, Medical Supplies, CMEF IVD and CMEF IT, which will serve an expedient acquisition rostrum.

The CMEF Imaging Area, as being allocated with the largest floorage of 18,000 square meters accommodating 15 product categories and over 30 assortments, is primarily focused on multi-modality medical image fusion. The product assortments cover domains of radiology, ultrasound, nuclear medicine and interventionology study. The equipment featured are from reputed enterprises domestic and abroad such as GE, Siemens Healthcare China, Philips, Dalian Xinhua Medical Equipment, Mindray Bio-Medical Electronic, Neusoft Medical Systems, Beijing Wandong Medical Equipment, Carestream Health, JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY, Shenzhen Anke High-tech, Shimadzu International Trading (Shanghai), Shanghai Medical, Perlong Group, FUJIFILM Medical Systems (Shanghai), and ALOKA INTERNATIONAL TRADING (SHANGHAI). These features have made CMEF 2010 the best platform for acquisition, expedition and procurement of medical equipment, as well as academic interactions. It offers an unparallel choice for product promotion, sales channel establishment and leading edge product announcement.

A brand new Hospital Building Area will be featured in CMEF 2010-Shenyang for the investment, planning, design, construction, operation, management and renovation of hospitals. Added with forums and exhibitory

reciprocating opportunities, this is to provide a decisive interaction platform for experts, managerial staffs, enterprise units and professionals of Chinese hospital building industry to exchange and explore the latest disposition and hot topics in this aspect.

As the largest fair organizer of medical equipment and related products and services in the Asia-pacific region, CMEF is the most prominent exhibition of its kind. It has profuse contents and keynote conferential forums for both business reciprocating and academic exchanges.

The CMEF 2010-Shenyang will continue this course by organizing many forum activities for advanced academic discussions and learning and training of medical professionals in this fair. It is going to sponsor two added keynote forums plus seminars -- China Medical Device Industry Development Summit and Health Care System Solution Forum, as a comprehensive platform for business interaction, academic exchange and information sharing for exhibition participants and fair audience. This platform, through year's endeavors and growth, has become the best platform to bridge the academic and business as well as international collaborations. CMEF and its co-organized forums moderated during the exhibition, together, reflect the leading edge information and the latest market trend of the industry.

The CMEF 2010-Shenyang will also continuously organize the "11th International Component Manufacturing & Design Show" (ICMD) with a reciprocating and collaboration platform to channel the medical equipment manufacturers and its up-streams. CMEF believes this cross-promotion and joint-development advocacy arrangement will facilitate the commercialization and shorten the time-to-market of new advanced medical equipment and products.

Information on CMEF AUTUMN 2010 online:
<http://en.cmef.com.cn/>

HOPITAL EXPO - INTERMEDICA 2010 Post show report - Key figures and trends

« An event that provides complete keys to understand and act on major healthcare issues and perspectives. »

« HOPITAL EXPO: the place to share and debate on strategic issues that will determine tomorrow's hospital performance. »

- 700 exhibitors
- 21,500 visitors (without exhibitors)
- 3,870 forum, congresses and workshops attendees
- 159 journalists
- 366 media releases



• **HOPITAL EXPO, a renewed edition :**
With its unique institutional base, HOPITAL EXPO remains the meeting place for key actors of the health sector.

• **HOPITAL EXPO is :**
A unique moment to share about Hospital world as well as a must attend event for health professionals: information about every health sector, novelties, VIPs, breaking news debates:

- 8% of international visitors from 21 countries (most represented countries: Belgium, Switzerland, Germany, Algeria and UK)
- 64 Foreign exhibitors from Germany, UK, Spain, Korea, Taiwan, USA
- Countries Pavilions were present on the exhibition from Malaysia, Pakistan, China and Austria.
- Creating free training courses and workshops on the exhibition areas:

- Well-being & Human resources area
- Sustainable Development area
- Medical Equipment & Technology area
- Hospital Logistics area

Visitors attendance statistics:

- 21,500 qualified visitors for both exhibitions
- 3,870 training courses attendees
- 38 % of the visitors stated that they came to prepare a call for tender
- 76% of the visitors were looking for new suppliers and 92% keeping updated with new products developments and trends
- 65% came to the exhibition to find specific solutions to their needs

For more information, visit www.hopitalexpo.com

ECR 2011: The Very Best in Radiological Science, Education and Technology

On March 3–7, 2011, the European Congress of Radiology (ECR) will once more open its doors at the Austria Center Vienna to provide another expertly assembled programme of sessions, a huge accompanying exhibition and the usual range of unique peripheral services. As always at the annual meeting of the European Society of Radiology (ESR), delegates can expect to be treated to the very best in radiological science, education and technology.

Among the many highlights of a packed ECR 2011 programme will be brand new categorical courses on musculoskeletal MRI and the importance of clinical knowledge, new mini courses focusing on the pancreas and oncologic imaging, and a selection of sessions held in collaboration with other societies. The European organisation for Research and Treatment of Cancer (EORTC), the European Association of Nuclear Medicine (EANM), and the Radiological Society of North America (RSNA) will all host joint sessions with the ESR, the former and latter of which will focus on oncology. The popular 'ESR Meets' programme, will also see the United European Gastroenterology Federation (UEGF) at ECR 2011, representing gastroenterology as the programme's partner discipline, with the radiological societies of France, Brazil and Iran also taking part and presenting their own sessions.

Outside of the lecture halls, the congress will boast another huge technical exhibition, with more than 300 exhibitors in the field of medical imaging coming from all over the globe to present their most recent developments. Companies from the smallest publishers to household names like

Siemens, GE Healthcare and Philips, will occupy 26,000m² of exhibition space for the duration of the congress, giving delegates an unrivalled opportunity to catch up with the industry that drives radiology forward.

With a whole host of additional onsite features, ranging from interactive sessions and free e-learning tools, to local arts and culture advice, the ECR offers a thoroughly complete experience for any radiologist. Greatly reduced fees for early registration and the convenience of the ESR's own online accommodation booking platform provide just two more reasons not to miss out.

Register online now and be a part of the most innovative imaging meeting in the world.

Registration:
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Expansion of the Brazilian healthcare market increases expectations for HOSPITALAR fair



Brazilian healthcare market has been showing accelerated growth over the last few years, thanks to the constant expansion of hospitals and health services providers that invest in equipment, expansions and new ventures. Sixth largest private health market in the world, Brazil currently has 192 million inhabitants, of which 43.2 million have health insurance. Of the nearly 7 thousand Brazilian hospitals, 70% are private and 30% are public.

The health sector turnover in Brazil is US\$ 133.1 billion a year (about 8% of the GDP).

The supplying industry increases its income and conquers new markets, with positive prospects both for domestic sales and exports. External sales added up to US\$ 541 million in 2009. Concerning the imports of medical-hospital products, it has reached US\$ 2.8 billion in 2009 and showing signs of continuing growth due to investments in equipment and in the construction of new hospitals. As for the Brazilian government, it continues investing in the sector and the budget of the Ministry of Health for 2010 reaches US\$ 38.7 billion.

This positive scenario, in addition to the strategic position of HOSPITALAR – largest gathering of the health sector in America –, increases the expectation of exhibitors and visitors regarding the 18th edition of the fair, scheduled for May 24 and 27, 2011, in São Paulo – Brazil.

HOSPITALAR 2011 – International Fair of Products, Equipment, Services and Technology for Hospitals, Laboratories, Pharmacies, Clinics and Medical Offices, will convene 1,250 exhibitors, including over 500 foreign companies, representing 36 countries. In 5 halls and an exhibiting area with over 82,000 sqm, directors of hospitals, clinics, laboratories and medical

offices, physicians, nurses, importers and distributors will get to know the most important launches of the international industry of medical, hospital and dental products and services.

For 2011, the organizers expect to surpass the 89,000 professional visits recorded in 2010. International attendance increased 22% in 2010 edition, representing 54 countries. From the 15 most representative countries among the visitors of the latest edition of HOSPITALAR, 12 were Latin American, what reaffirms the strength of the fair as a business platform for buyers from Latin America.

HOSPITALAR will hold specific event for the Nursing sector

Aware of the strategic importance of the Nursing sector in the healthcare scenario, HOSPITALAR announces a new event, totally focused on that segment.

EXPO ENFERMAGEM – 1st International Fair of Nursing Products and Services will be held from October 4 to 7, 2011, at Palácio de Convenções do Anhembi, in São Paulo – Brazil.

Following the concept of fair + forum adopted by HOSPITALAR, EXPO ENFERMAGEM will gather leading companies of the market of nursing products and services that will show their novelties for a highly qualified public, composed by nurses and nursing technicians and assistants. In Brazil, there are currently around 1.4 million acting nursing professionals, of which around 350,000 are in the State of São Paulo.

The new event counts on the partnership of COREN-SP - Regional Council of Nursing, which will hold, on the same date and venue, the 2nd Nursing Forum of COREN-SP, group of lectures and activities for professional updating, management and integration with all the clinical staff of the hospitals.

Visit www.hospitalar.com

The Perfect Place to Expand Your Business

KIMES will bring you to the great opportunity, we provide the platform for future success of your business.

Since first edition of KIMES in 1980, the show has been grown up with Korean medical and healthcare industry. We tried to make the show as the fair place for the entire people who engaged in the industry through out gathering of advanced medical and healthcare related items and sharing of the newest information.

Recently, Korean government appointed medical industry as the one of the leading industry that propelled Korean economy in future, and the government provided blueprint of financial and political backing for the industry.



Moreover, globalization of medical healthcare service industry sector is the main issue in Korea nowadays, and to achieve the specialization of the industry, it should be based on sharing of information and visions.

Current global economy downturn caused many difficulties on the entire Korean economy and the needs of development of new technologies and new market are important than any other time.

Regardless of today's global shifts, it is clearly recognized that trade exhibitions are still of prime importance to the economy – and in some cases they are even more important than ever before. Especially in times of crisis, domestic and international economic partners need exhibition platforms to send positive signals to their strategic markets to launch innovative products, to discuss crisis-management measures and using this knowledge respond quickly, flexibly and correctly.

KIMES 2011 is held at a time like this to provide the vision for the future to our medical industry with 1,200 exhibitors from 35 countries and around 40 sessions for seminars.

Emphasis will be put on ensuring that there is a balance between the different exhibition categories, as KIMES is a total healthcare related show. While it is important to include innovative new technologies, involving digitalization and personalization, it is also important that KIMES shows the direction in which the entire industry is heading.

The current economic situation may provide more opportunities in the Korean market for international trade. Taking advantage of a critical situation and seizing the opportunity to make inroads into growing markets is the way to success for most businesses.

We firmly believe that KIMES is the right platform to shift up the standards of Korean medical and hospital industry and we will make the KIMES 2011 as the specialized and differentiated exhibition that essential for our industry.

Korea E & Ex Inc. (KIMES 2011 organiser)
Rm. 2001, KWTC, Samsung-dong, Gangnam-gu, Seoul, Korea
Tel: +82 2 551 0102 Fax: +82 2 551 0103
Website: www.kimes.kr

Syrian Medicare 2010 The 10th Annual Int'l Medical Exhibition & Conference

On Wednesday 16th June 2010 at 06:00 p.m. H. E. Syrian Minister of Health inaugurated the regional biggest medical event Syrian Medicare 2010 and the parallel event Syrian Medical Association Scientific Conference, both held and organized by United for Int'l Exhibitions & Conferences in cooperation with the Scientific Council for Pharmaceutical Industries and Syrian Medical Association.

10 Years of Continuous Success

After ten years of continuous success, Syrian Medicare has become a central appointment for meeting and achieving the increasing demands and requirements of the medical field by highlighting the its latest developments. The event is also considered an effective marketing tool in order to meet specialized customers such as Exporters, Importers, Doctors, Decision Makers, Businessmen and Medical Professionals. Syrian Medicare is recommended by all private and public medical and pharmaceutical sectors in the Arab and foreign countries.

Wide Participation:

The 10th int'l session of Syrian Medicare has exceeded over 8,000 sq/m in space area. The show hosted more than 415 international companies and brand names from 40 countries as well as 50 international participating companies from 12 countries by an increasing figure of 35% of the total participant.

The Conference

Due to the important role given to Syrian Medicare Exhibition and to the scientific conference, the Syrian Medical Association held the 4th annual

Syrian Medical Association scientific conference simultaneously with Syrian Medicare 2010 exhibition. The Medical conference has covered a wide range of important topics on the latest developments in the medical and pharmaceutical sectors with the participation of elite professors, specialists and doctors.



The Scientific Conference Main Topics:

- The Latest Developments in Cardiovascular Diseases
- Laparoscopic Surgery
- Blood Transfusion: Safety - Quality – Future Vision
- Breast Cancer
- Obstetrics and Gynecology + Gynecological Oncology
- The Recent Advances in Radiotherapy

Distinguished Arabic & Foreign delegations at Syrian Medicare:

Syrian Medicare 2010 hosted many international business delegations such as FENIN and the Tunisian delegation of Doctors, Hospital Directors and other companies related to the medical and pharmaceutical fields that profitably attended the show.

For detailed information on the up-coming show visit:
www.syrianmedicare.com



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Foc



Focus on:

The Medical Market in the European Union

Europe in figures

Population:	497 million
GDP (in million € at market prices):	12,503,337
GDP per capita (PPS in €):	25,100
GDP growth (in %):	0.8%
Inflation (in %):	3.7%
Unemployment (in %):	7%
Exports: Goods (in million €):	3,900,941
Imports: Goods (in million €):	4,020,278
Exports: Services (in million €):	1,250,910
Imports: Services (in million €):	1,087,091
Total trade balance (in million €):	44,483
Total Trade (in million €):	10,259,220
Government Financial Balance (as % of GDP):	2.3%
Government debt (as % of GDP):	61.5%
Total trade (as % of GDP):	82.1%

Source: EFTA, Economic Indicators 2008
<http://www.efta.int/statistics/statistical-data.aspx>

Healthcare Provision in the EU

With a population of about 500 million projected to reach 528 million by 2030, and an estimated GDP of € 12.5 million in 2008, the European Union (EU) has 27 member countries marked by different resources and historical backgrounds. Considering the challenges posed by the task of ensuring and harmonizing the delivery of healthcare in all its member countries, the EU has set a framework for the construction of a common health policy. This programme, outlined in the strategy "Together for health: a strategic approach for the EU 2008-2013" adopted on 23 October 2007, individuates as main goals the improvement of citizens' health security, the promotion of health and reduction of inequalities in its delivery, as well as the dissemination of health information and knowledge. Steps planned to reach such objectives include a closer focus on patients and integration of health into all policy areas, with a financial support of EUR 321.5 million for the mentioned period.

The healthcare scenario offered by the different regions of the EU is quite heterogeneous: although public provision of healthcare and comprehensive insurance systems are widespread across all Europe, in Western countries public health systems have largely been integrated by the private sector, both in inpatient and outpatient care. As far as health insurance is concerned, along with general schemes covering all citizens private insurance is being chosen in many countries as a mean to get additional coverage for services not included in public funded care, either through employment contribution or personal funds.

Sectors where Western European citizens tend to seek private care are diagnostics, cosmetic surgery, orthopedics, ophthalmology, dental treatments as well as several other procedures mainly performed on an out-patient basis. This process, though slower, is occurring also in Eastern Europe, but conditions are different as most countries in this region entered the EU quite recently (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia in 2004, Bulgaria and Romania in 2007).

As explained by the European Hospital and Healthcare Federation (HOPE) in the 2009 study "Hospitals in the 27 Member States of the European Union", all of these countries except for Cyprus and Malta inherited post-soviet health systems with a series of shared problems such as a high number of hospitals lacking adequate funding and supply of modern equipment. HOPE warns that, although the gap has been partially filled by the improvements brought since the dissolution of the soviet bloc, much remains to be done in terms of accessibility of quality healthcare to all groups of the population.

Generally speaking, the international financial crisis considerably reduced the availability of public funds for healthcare, pushing governments to adopt stricter cost-containment measures and look for a more efficient management of resources. This means that more treatments are being provided on an outpatient rather than inpatient basis, while the participation of the private sector is growing across all Europe as the national health systems outsource services to private providers

and reduce those who are covered by social insurances and public funds. Private schemes, in fact, are ever more involved in healthcare financing by taking under their coverage procedures that were previously included in public funding.

Unaffected by the widespread reduction in the number of beds in public facilities, the number of beds in private hospitals is increasing overall with higher rates in Germany (46% of total bed capacity) and Spain (about half of total bed capacity), according to figures reported by HBS Consulting firm. More and more patients prefer to get faster and more specialized private care.

EU Health Resources

Health expenditure across Europe: Total health expenditure is defined by HOPE as "the consumption of healthcare goods and services plus capital investments in healthcare infrastructure, given by the sum of public and private expenditure on health".

Figures for the year 2007 show that per capita total health expenditure in the EU was valued at average 2,788 US\$, ranging from 977 US\$ for the EU12 group to 3,190 US\$ for EU15. In the period 2001-2007, HOPE reports an increased per capita health expenditure in all EU countries with particularly high growth rates in the Baltic States (Latvia +139%, Lithuania +102%, Estonia +100%) and in Slovakia (+134%).

Inpatient care expenditure accounted for 34% of total EU healthcare spending, but percentages varied significantly in the different countries, ranging from about 21% in Slovakia and Portugal, to about 45% in Italy and Latvia, followed by Austria, Netherlands and Luxembourg at nearly 40%. The share of inpatient care expenditure in Germany, France, Belgium and Finland remained around 35-37%, while lower rates (about 30% of total expenditure on health) were registered in Poland, Hungary, Spain, Sweden and Denmark. HOPE reports that inpatient care expenditure in the above mentioned period remained stable or decreased, while total health expenditure has maintained its growing trend.

Healthcare funding: Referring to a classification adopted by the European Commission there are basically three main methods of healthcare funding among European countries, sharing as a common feature the mix of various resources and the control of most funds, either direct or indirect, by state administration. These are a public taxation-based model, a compulsory social insurance-based model and a third model based on a combination of standard social and voluntary insurance. In addition to that, various types of cost-sharing schemes involving patient's contribution are spread in most of EU member countries.

According to figures reported on Eurostat yearbook 2010, social security funds account for about three fifths of healthcare expenditure in several EU countries, with Czech Republic (81%) and the Netherlands (77%) leading. In countries such as Denmark and Sweden most financing comes from other government sources, while this percentage is reduced to about 50% in Portugal, Spain, Finland and Latvia.



Out-of-pocket payment contributed for less than 10% of the total in the Netherlands and France, to over two fifths in Bulgaria and Latvia (2004 data), and nearly half the total in Cyprus. Private insurance plans, though increasing their market share, are generally below 10% of the total except for Slovenia and France where the percentage is over 13%.

Workforce and hospital beds: The number of active physicians has been growing almost everywhere in the EU over the last decade, except for Italy, Hungary, Poland and Lithuania. Latest available data by Eurostat rank Belgium at the top with 405 physicians per 100 000 inhabitants, followed by Austria with 374.

Hospital beds, on the contrary, have been decreasing, particularly in Baltic States, Sweden, Luxembourg, Bulgaria and Italy. To give only some examples, between 1998 and 2007 there was a reduction by 22.3% in curative care beds and 26.8% in psychiatric beds (data for EU-27). The higher number of procedures transferred to outpatient care and the reduction in average length of hospital stay due to improvement in post-operative care and rehabilitation treatments are among the main factors influencing this trend.

An outlook at the medical devices market in Europe

Figures sourced by Eucomed (European Medical Technology Industry association) value the EU medical market at € 72.6 billion in 2007, the second largest market after the US (€ 98 billion), accounting for about one third of the world market share. In 2007, the average expenditure on medical technology was valued at 6.8% of total healthcare expenditure in the EU. The medical industry has an important role in European economy, employing about 530,000 highly skilled workers with an annual growth rate of 5-6%. R&D enjoys high investment rates, up to 8% of annual sales revenues.

According to Eucomed data, small and medium enterprises (SMEs) account for 80% of the 11,000 companies involved in the medical devices sector. Germany is by far the main producer of medical equipment and technology, being also the main exporter (€ 14 billion in 2007) and importer (€ 9.2 billion), followed by France, UK, Ireland, Sweden, Denmark and Finland. Spain and Italy are among the main importers after Germany, France and UK.

Several factors need to be considered when exploring possibilities for growth in the European medical devices market. First of all, population and demography trends: Eurostat projections forecast that people aged 65 or over will account for 30% of the EU-27's population by 2060, compared with current 17% share (2008), while the group of people aged 80 years or more for the same year is

estimated to account for 12%. The increasing number of elderly persons means a continuous demand for healthcare services such as long-term care and nursing. In addition to that, it must be considered that 30.8 million foreigners live in the EU as per 2008 estimate, a share of 6.2% of the total population, and immigration contributes to the growth of population needing health services.

Changes in payment system and technology advances in diagnosis and treatment are further drivers for growth, considering also the increased movement of patients across borders seeking for health treatment abroad that is being supported by EU policies aimed at improving connections between Member States' health systems and services.

According to PA Consulting agency, the current methods to decide reimbursement from treatments are likely to shift gradually towards payments tailored on treatments' effectiveness on the single patient, taking advantage of the technology progress in monitoring and analyzing information.

Storage and circulation of data will play an ever increasing part in the future health systems, paving the way for the expansion of IT global protagonists into the healthcare domain. Home care and personal healthcare management are in fact already benefiting from the integration between IT and health services, as proved by the growth of e-health and telemedicine applications available to patients offering a cost-saving alternative to traditional healthcare delivery.

Health consciousness is improving among European societies, supported by public programmes and initiatives aimed at encouraging prevention and early detection as means of reducing costs while promoting correct health behaviors. Better informed patients and the availability of ever more personalized, patient-focused assessment and care are among the benefits that will derive from a stronger integration between healthcare and information industries.

The market will present an ever more interconnected scenario, where monitoring, diagnostic and curative procedures increasingly cooperate towards what can be defined as an "holistic approach" to healthcare. Yet, it must not yet be forgotten that the consequences of crisis and recession will affect the EU medical market for some times still, in terms of delays in replacement of equipment and slowdown of capital expenditure. Moreover, in countries subjected to a rise in unemployment rates, patients are often cutting or postponing specialized visits, elective surgery and all treatments that are not immediately necessary.

This, however, won't prevent many sectors from experiencing a partial or substantial growth: to name only a few, cardiology, orthopedics, imaging, diagnostics, robotised and image-guided/minimally invasive surgery, cosmetic surgery and obesity treatment, neurology, urology, home care and telemedicine applications all offer a good potential in terms of market expansion within the EU.





Promising sectors for innovation and growth

Among the most innovative sectors, robotics is gaining momentum as privileged fields to test and develop new healthcare technologies. The study "Robotics in Healthcare" (European Commission, Directorate General Information Society and Media, 2008) provides a broad definition of robotics as the "application of technology whereby systems are able to perform coordinated mechatronic actions (force or movement) on the basis of processing information acquired through sensor technology".

The potential offered by robotics is of the utmost importance in terms of sustainable and affordable provision of quality healthcare, but the field is still at an early stage, needing investment and support from stakeholders to move from laboratory and trials to industry and practical application.

The EC study focuses on six main areas that deserve deeper investigation and may meet the interest of the market: smart medical capsules, Robotised surgery, intelligent prosthetics, Robotised motor coordination analysis and therapy, robot-assisted mental, cognitive and social therapy and Robotised patient monitoring systems.

- Smart medical capsules allow endoscopy treatments more comfortable than traditional invasive probes. The patient swallows the smart medical capsule as a 'pill' that makes pictures of internal systems while travelling through the body. A Robotised capsule could move itself, or be externally steered, to have a closer look at internal tissues, take samples or even destroy unwanted tissue.
- Robotised surgery will facilitate minimally invasive interventions through the automation of surgical tasks and could also be used in remote tele-surgery, preoperative planning, surgical training and simulation and image-guided surgery. Different robotic systems may be integrated in platforms assisting surgeons and able to perform surgery autonomously.
- Intelligent prosthetics adopts control systems that facilitate natural movement and intuitive control of arm and leg prostheses, preferably with the same sub-conscious control as for natural limbs. Future applications may include control by nerve signals from peripheral system and brain interfacing.
- Robotised motor coordination analysis and therapy can bring an important contribution to the treatment of patients with traumatized motor control, supporting the training given by a physical therapist by inducing preinstalled movements or mirror movements for which unaffected control is still available, thus opening the way to the restoration of central motor coordination.
- Robot-assisted mental, cognitive and social therapy offers new approaches to the treatment of mental, cognitive and social handicaps (such as autism or senile dementia). Robotic systems can interact with the person by communicative reactions such as sounds, colors, face expressions, they can stimulate playful reactions and games and learn to adapt to each person.
- Robotised patient monitoring systems in home care might be useful when remote monitoring cannot determine the urgency of an unusual situation, obliging the doctor or nurse to go to the patient's home. Robotised identification of alarming situations more affordable and efficient home care.

Future developments of robotics will affect almost all fields of medical treatments, from surgery to diagnostics, to home-treated patients monitoring, to the employment of robotics in some tasks of nursing care to face staff shortages. A critical issue is how these new complex systems will be integrated in healthcare provision by taking into consideration ethical and legal aspects, but research programmes all across Europe show that the interest towards robotics is alive both from science and industry, making the EU a potential global leader in this innovative area.

Telemedicine and e-health constitute perhaps the most relevant area currently attracting investment and research projects across Europe: the EU Information and Communication Technologies (ICT) Unit for Health states that since the mission "eHealth Enabled Citizen-Centered Care", was launched in 1989, over 450 projects have been supported with more than €1 billion funds. Research initially focused on telemedicine, homecare, electronic health records and regional health information networks, but the agenda has been extended to a more patient-based approach including personal health systems, patient safety, and predictive medicine. In December 2007, the report "Accelerating the Development of the eHealth Market Europe" (European Commission, DG Information Society and Media) identified eHealth as a sector where EU industry can

affirm its competitiveness and leading position in the international market, with high growth potential for innovative products and technological solutions.

Besides dealing with regulatory obstacles, legal and ethical aspects and language barriers, however, EU countries must strengthen their infrastructure for eHealth, including broadband Internet and communications, electronic health records and e-prescribing, patient summaries. In Denmark, Netherlands, Germany and in the Scandinavian countries these efforts have been particularly notable.

In a recent report named "Business Models for eHealth" (February 2010) the Information Society and Media Directorate stressed the importance to remove barriers to the large European market for eHealth. Estimated at € 14.269 million in 2008 and projected to reach € 15.619 million by 2012, with a compounded annual growth rate of 2.9%, the EU eHealth market includes large European-based companies specialized in e-health solutions along with 5,000 European SMEs. France, Germany, Italy, Spain and the United Kingdom are currently the main eHealth markets.

eHealth comprises several subsectors contributing on different scales to its revenues and growth. The main categories are:

- Clinical Information System (CIS), including specialized tools for health professionals within healthcare institutions (e.g. hospitals) such as radiology and nursing information systems, medical imaging, computer-assisted diagnosis, surgery training and planning systems, as well as tools for primary care and/or for outside care institutions, such as general practitioner (GP) and pharmacy information systems.
- Secondary Usage Non-clinical Systems (SUNCS), including systems for health education and health promotion of patients/citizens (health portals or online health information services), specialized systems for researchers and public health data collection and analysis (biostatistical programs for infectious diseases, drug development, and outcomes analysis), and support systems to clinical processes not directly used by patients or healthcare professionals (supply chain management, scheduling systems, billing systems, administrative and management systems).
- Telemedicine Personalised health systems and services (disease management services, remote patient monitoring, teleconsultation, telecare, telemedicine and teleradiology)
- Integrated Health Clinical Information Network (IHCIN), meaning distributed electronic health record systems and associated services, such as e-prescriptions or e-referrals.

According to estimates mentioned in the report, in 2008 Secondary Usage Non-clinical Systems (SUNCS) accounted for 71.6% of the total eHealth market in Europe, Clinical Information Systems (CIS) for 13.5% and Integrated Health Clinical Information Networks (IHCIN) for about 5%, followed by telemedicine at 0.9%.

Forecasted trends in the eHealth market include a growing demand for Clinical Information Systems and Integrated Healthcare Clinical Information systems (IHCIN), given the need for data sharing among healthcare delivery organisations. These two subsectors are expected to account for 80% of eHealth market growth up to 2012. Though considerably smaller, the market for telemedicine systems and applications will similarly continue to grow in the long term.

Promising sectors for EU medical devices market also include cardiology, orthopedics, cosmetic surgery and homecare, according to a presentation by Frost & Sullivan.

Cardiology is dominated by pacemakers and interventional products such as angioplasty and stent technologies, and products related to cardiac rhythm management. Interest towards minimally invasive devices and robot-aided surgery is increasing according to a press release from MEDICA 2010, bringing forward as an instance the treatment of atrial fibrillation. Generally speaking, the market for cardiovascular devices is defined as "relatively recession proof" and expected to remain quite stable, considering factors as population ageing and better information on heart-related diseases, or even growing in some sub-segments most sensitive to the use of innovative technologies.

Orthopedics and prostheses as well are fields involved in the development of minimally invasive procedures and image guided surgery. The overall situation of the market is not flourishing, having registered slowdown in demand for orthopedic treatments and joint reconstructions as part of the general trend in delaying surgery under pressure of the crisis. Among the most interesting market segments, however, there are spinal surgery and bioabsorbable structures, along with the market for less common joint such as elbow, wrist and digit replacement. New devices able to transmit wireless information on joint position and performance are also being introduced, such as implants able to monitor parameters in the surrounding bone.

Home care and cosmetic surgery are among the other expanding sectors. Europe is the second market for cosmetic surgery procedures worldwide, with Spain leading a demand that is increasing almost uniformly in Western and Eastern Europe, helped by lower prices and easier availability. Home care and non-hospital therapies are cost-saving alternatives to in-patient treatment, boosted by the reductions in hospitals and beds and the advances in remote monitoring technologies. Rising elderly population makes a broader number of patients choose home care as an effective solution to get personalized care.

What is private sector's role in this evolving scenario?

HBS Consulting, in the online report "The Role of the Private Sector in the European Healthcare Market", forecasts that by 2020 private providers will account for half of the health market. New technologies are adopted faster in the private sector, creating an opportunity for manufacturers in this field and meanwhile supporting further investment in research and development of competitive innovative products. Readiness to experiment and introduce new technologies and flexibility in reacting to market needs are therefore important advantages offered by private health providers.

There is however a need to differentiate sales strategies according to the target: besides the difference between private and public purchases, even in the private sector there is a mosaic of providers with different requirements, from large hospitals making large orders directly to manufacturer through group organizations or co-operatives, or centralized agencies, to small clinics with specific needs for niche devices and equipment.

Medical devices within Europe are regulated under the following directives:
 In Vitro Diagnostic Devices (IVDD) – This regulates all diagnostic devices and supplies that are used away from the patient.
 Active Implantable Medical Devices (AIMD) – This directive covers all active devices and accessories meant to be permanently implanted in patients.
 The Medical Devices Directive (MDD) – This directive controls all other general medical devices not covered by the above directives.

For detailed information on recent amendments to the EU directives on Medical Devices, see the article at page 38-39.

Sources:

- EU Statistical Office - EUROSTAT: <http://epp.eurostat.ec.europa.eu>
- EFTA (European Free Trade Association): www.efta.int
- HOPE (European Hospital and Healthcare Federation): www.hope.be
- EUROPEAN COMMISSION, Directorate General - Health and Consumer Protection: <http://ec.europa.eu/health-eu>
- EUROPEAN COMMISSION, Directorate General - Information Society and Media: http://ec.europa.eu/dgs/information_society/index_en.htm
- EUCOMED (European Medical Technology Industry): www.eucomed.org
- HBS Consulting: www.hbs-consulting.com
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Interview

Besides the initial diagnosis of cancer itself, alopecia continues to be the most traumatic and distressing psychological side effect that many cancer patients will experience. Since its introduction in 1997, thousands of patients have benefited from Paxman Scalp Cooling systems. We speak to Richard J. Paxman BSc, Operations Director, Paxman Coolers Ltd, the UK-based company behind the Paxman Scalp Cooling systems, about this award winning product.

How does the scalp cooler work?

Cancer chemotherapy affects rapidly dividing cells and at any given time, 90 per cent of human hair follicles are in the actively dividing phase. Hair loss frequently occurs due to partial or total atrophy of the hair root bulb, causing constriction of the hair shaft, which then breaks off easily. Cooling the scalp during selected chemotherapy regimes has been shown to reduce or prevent otherwise inevitable total hair loss. By cooling the scalp to around 15-20 degrees Celsius vasoconstriction occurs, which reduces blood flow to the hair follicles during peak plasma concentrations of the chemotherapeutic agents and so reduces cellular uptake of these agents. A second rationale is reduced biochemical activity, which makes the hair follicles less susceptible to damage by chemotherapeutic agents.

How long has this technology been available? What makes your technology stand out?

Developed after the managing director's wife had lost all her hair during her cancer treatment, using the help of his brother, his engineering knowledge and the resources of his business, the Paxman Scalp Cooler was created. Following trials at Huddersfield Royal Infirmary the product was launched and company formed in 1997. The first systems were sold to hospitals such as Christies in Manchester, St Mary's Hospital, Portsmouth, Stoke Mandeville Hospital, and The Derriford Hospital, Plymouth - all of which are still in use today - a testimony to the reliability and success of the product.

Other systems based on this principle utilise packs of crushed ice and frozen gel caps. These have the disadvantage of being uncomfortable, heavy to wear and are applied to the scalp at an unbearable temperature of -25°C which heats rapidly when in contact with the scalp, and perhaps more important however is the application and monitoring aspect, which is very time consuming for nursing staff.

Thermo circular systems utilised a cold cap of circulating glycol in the past as long ago as 1982. Paxman Coolers have applied the same principles using modern technology to produce the Paxman Scalp Cooler. A system that works, is user friendly, is a cost effective way to reduce the need to supply wigs, and has been accepted by doctors, nursing staff and patients alike. Previous problems associated with cold therapy treatments have been eliminated.

The system has received the Millennium Product Award for Innovation. Our new ORBIS Paxman Scalp cooler will be launched at Medica 2010 which will offer improved efficacy, increased patient tolerance whilst remaining easy to use and compact.

Can you give me some clinical data on the efficiency of this technology?

UK trials for the Paxman Scalp Cooler have shown a 70-80 per cent success rate in breast cancer patients. In other trials measuring patient comfort, acceptability and side effects, patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling.

What type of patient is a good candidate for the scalp cooler?

Cold cap treatment can be used with a range of alopecia causing chemotherapy and a number of different types of cancer types in both men and women.

Where is this technology currently distributed to?

The equipment is currently distributed to UK, Australia, Canada, Cyprus, Denmark, Egypt, France, Finland, Greece, Holland, Belgium, Ireland, Italy, Japan, Norway, Portugal, Spain, Sweden, Switzerland. We are currently working towards distribution agreements and registration of the equipment with Korea, Japan, Russia, China, Slovakia, Czech Republic, Poland, India, Brazil, and the UAE. After a very successful exhibition at Arab Health 2010 we are looking to build new partnerships in the Middle East and looking to build further relationships with European Distributors at Medica 2010.

How will hospitals and patients in the benefit from this technology?

Besides the initial diagnosis of cancer itself, alopecia continues to be the most traumatic and distressing psychological side effect that many cancer patients will experience. Alopecia is seen as a constant reminder of the disease and can cause negative changes in body image, decreased social activity, and altered interpersonal relationships. These practical and emotional problems can result

in a patient's reluctance, even refusal, to accept treatment.

By reducing or preventing hair loss in cancer patients this should benefit both the patients and their families' quality of life. Often, this side effect, can lead to the refusal of chemotherapy treatment. This is an added benefit to patient care for the hospitals and provides patients the choice not to lose their hair.



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Visitors will be able to see first hand a pioneering new device that offers a quicker, more accurate detection of cervical cancer. **Zilico's** hand-held device measures the resistivity of cells and detects any changes as they progress from normal through to cancerous. It offers a more accurate detection of cervical cancer in real time; removing several weeks of waiting for a diagnosis.

Also on the pavilion **Sidhil** will be showcasing their advanced acute hospital bed, that combines practicality, world-class infection control and advanced ergonomics. The Independence Innov8 has been designed exclusively to meet the needs of hospital teams and patients around the world – making it one of the most comfortable, easy-to-use and practical hospital beds anywhere in the world.

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Surgical Innovations, who has recently been awarded a Queen's Award for Enterprise under the Innovation category, will also be at the show. Surgical Innovations will be exhibiting their pioneering range of Resposable® instrumentation - devices which combine both single use and reusable components to offer a cost effective but high quality solution.

Offering exhibitors much needed supplements throughout the exhibition will be **Principle Healthcare** - one of the UK's leading vitamin, minerals and supplements producers. The company will be showcasing their unique range of vitamin and mineral supplements, which includes Biocalth, a unique ingredient proven to help deliver Calcium more efficiently to the bones.

Harvard Healthcare will be unveiling their first single use hip arthroscopy access system, together with a unique range of handheld disposable endoscopic instruments. The complete single use hip access system provides easy access into

the joint, eliminating the need for costly reusable hip arthroscopy instruments and reduces the problems associated with cleaning and re-sterilising narrow lumen instruments. Hip arthroscopy is a growing market and in just a few small incisions surgeons are able to insert instruments into the hip joint to trim bone and repair cartilage.

The next generation in hair loss reduction systems will also be showcased by **Paxman** for the second year in a row – a pioneering device that provides cancer patients with the best possible chance of retaining their hair whilst undergoing chemotherapy treatment. The loss of hair during cancer treatments is a traumatic and psychologically devastating side effect and a constant reminder of the disease.

Other regional companies at the show include Anetic Aid, Brenmoor, Foresite Diagnostics, Xiros /Neoligaments and Aegis Ltd.

If you would like to do business with any of the above companies please visit the Yorkshire Pavilion in Hall 16, stand G10 or register your interest by emailing j.price@medilink.co.uk

Are you a UK companies exhibiting at MEDICA?

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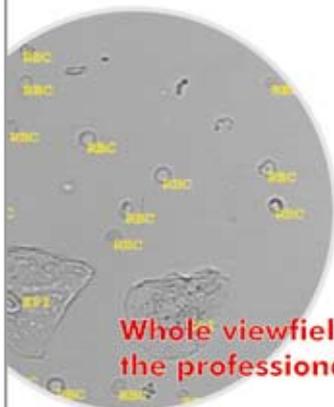
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Registration Of Medical Products in Russia



The registration of medical devices and medical equipment in Russia is challenging. Most problematic for foreign manufacturers seeking device registration is that Russia still relies on a system of product testing as a tool for determining product safety and efficiency. As Russia have its own national standards, such as testing which is required for products that already possess CE marking, US Food and Drug Administration 510(k) clearance or other national approvals. Even products that have been for sale on the US and European markets for many years require product testing to Russian standards as well.

Russian policy of requiring product testing in addition to obvious language issues are significant barriers for foreign companies to register medical equipment in the country. Since very few documents exist in English, it has sense to operate through a local partner familiar with the process and who can effectively navigate your registration.

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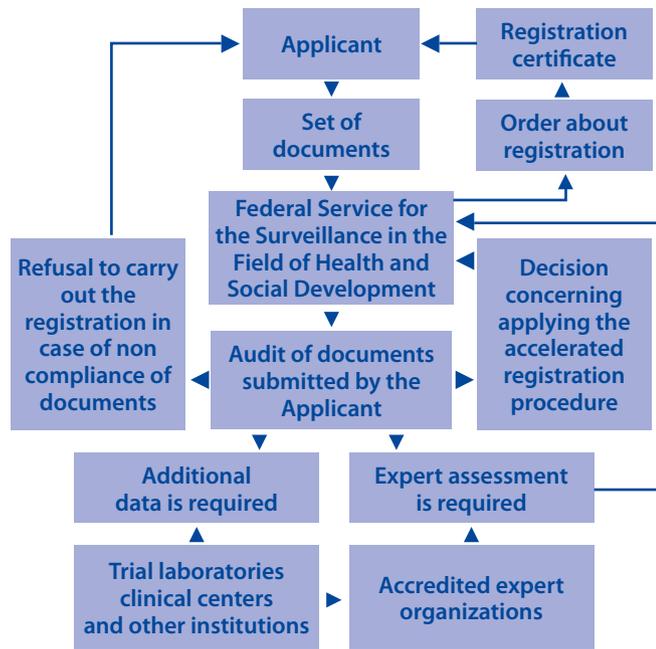
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Registration Process

Scheme for passing through the registration of medical equipment and medical articles of foreign production:



Russian Regulatory Authorities

Several major government entities currently oversee regulation of medical equipment and devices in Russia.

Roszdraznadzor - www.roszdraznadzor.ru

This is the short title of the Federal Service for Control of Healthcare and Social Development in the Russian Federation. This agency oversees all domestic and imported medical devices in Russia. It governs and controls the registration procedure, approves or rejects applications for state registration, and works to ensure clinical safety and efficiency of medical devices and medical equipment.

Gosstandart - www.gost.ru

Known as the Federal Agency for Technical Regulation and Metrology, this agency makes sure that medical equipment imported into Russia meets established Russian standards. This agency is responsible for GOST-R certification. Rospotrebnadzor - www.rospotrebnadzor.ru

Not to be confused with Roszdraznadzor, this is the Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection. This agency makes sure that products meet Russia's sanitary and epidemiological regulations for products that come into contact with the human body or which may otherwise negatively affect patients or doctors. They issue Sanitary-Epidemiological Conclusion (Hygiene Certificate).

Certification

To clear medical devices through Russian Customs, the products must also have one or both of the following certificates, which can only be issued after the Registration Certificate has been obtained. These include:

- Sanitary-Epidemiological Conclusion (Hygiene Certificate)
- GOST-R Quality Certificate



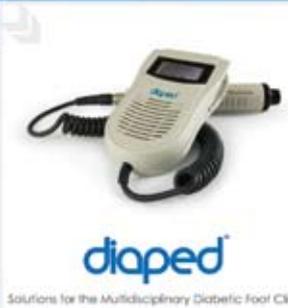
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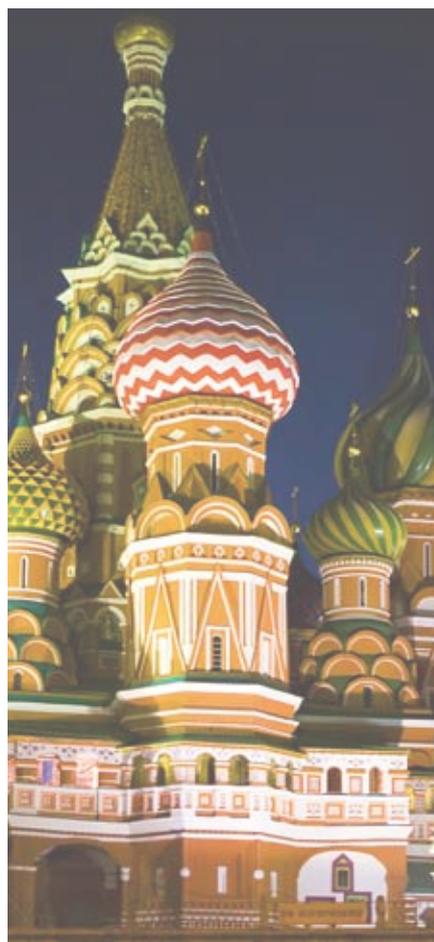
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Sanitary-Epidemiological Conclusion (Hygiene Certificate)

As noted, devices that come into contact with the human body and which may negatively affect patients or doctors must obtain a Sanitary-Epidemiological Conclusion, more commonly known as a Hygiene Certificate. This testing confirms that the product conforms to applicable hygienic standards and sanitary regulations in Russia.

For most products, a Sanitary-Epidemiological Conclusion (Hygiene Certificate) is valid for five years, but some products must be renewed each year. The certificate can be issued in the name of a distributor, but the manufacturer is the holder. The process for obtaining a Hygiene Certificate usually takes one to two months.

Manufacturers can request inspection of their production facilities so they can be issued a Hygienic Certificate for all of their manufactured products. This may be a wise choice for companies with numerous products. The inspection will focus on manufacturing conditions, raw material quality control, technological processes and safety/sanitary parameters of the final devices.

GOST-R Quality Certificate

The GOST-R Certificate is similar to a CE marking certificate and is issued to a manufacturer to confirm that the imported product meets Russian national quality standards. Products must pass tests that have to be carried out by a local testing body accredited by the GOST-R system. The tests of conformity with Russian safety requirements should also meet the Essential Requirements of the European Medical Devices Directive (93/42/EEC). Additional documents should be submitted for certification (e.g. brochures, product description, protocols, test reports from international test laboratories, safety certificates issued by international authorities, ISO 13485 certificate (if available), Declaration of Conformity with the list of product codes and product names, instructions for use and a risk analysis).

Once certification has been achieved, the device must carry the GOST-R symbol (the mark of conformity), which clearly demonstrates product compliance to the applicable Russian standards.

GOST-R Certificates are issued by a testing centre accredited by Gosstandart and are valid for one year (for a shipment or several shipments under one contract), or for three years if experts from Gosstandart visit and assess a foreign producer's manufacturing facility in the country of origin. The GOST-R Certificate usually takes one to three weeks to acquire after the Registration Certificate has been issued. Fortunately, for those companies that need to acquire the GOST-R and Hygienic Certificates, many of the required documents already gathered on the registration level.

List Of Documents Required For Registration And Certification Of Medical Devices At The Russian Federation

- Power of Attorney for the applicant. The manufacturer must officially authorize the applicant to conduct the registration on behalf of the manufacturer. This document must be notarized and legalized by a Russian Consulate office.

- The document of registration of the company in its country (The reference from the Chamber of Commerce Industry, Annual registration FDA or Certificate of Incorporation, Business License). This document must be notarized and legalized by a Russian Consulate office.

- Certificate confirming correspondence of medical product to the national or international norms and describing the conditions of its production (ISO 9001, 9002, 13485, 13488). This document must be notarized and legalized by a Russian Consulate office.

- Certificates of conformity of medical product to Directive 93/42/EEC and safety of product (EC Certificate, Declaration of Conformity, Free Sale Certificate, FDA Certificate) or document confirming the registration of medical device in the country of manufacturer or in other countries. This document must be notarized and legalized by a Russian Consulate office.

- Operator's manual or Description of medical product with instructions (Russian) (should be on the manufacturer blank stamped and signed; and CD).

- Advertising materials

- The nameplate on the manufacturer blank stamped and signed.

- Test Report for safety (IEC 60601-1, IEC 60601-1-2, ISO 10993 etc.) - it might be as well to give the complete report to lighten the technical examination at the testing laboratory (should be CD).

- Samples for the technical, toxicological tests.

NOTE: international rules of law of certifying are applied to the documents (apostil)

Timeline And Costs

The overall registration process for medical equipment usually takes between 3 to 8 months. It is difficult to estimate the total cost in advance because it should be calculated individually, depending on the class of risk and type of medical device. The registration certificate is issued without restriction of period of validity.

The total cost of dossier preparation, testing, translations, notary/apostille services, and other consulting fees typically starts from EUR 4,000. In some cases cost of registration could be reduced by including in one registration statement similar medical items. Actual costs need to be determined on a case-by-case basis.



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Changes within the new EU directive

(2007/47/EC) on CE marking of Medical Devices

Although the previous Medical Devices Directive 93/42EEC has not been radically changed, a series of clarifications and innovations have been added to improve the interpretation of procedures for the evaluation of products across Europe. The changes concern, among others, the essential requirements which medical devices must satisfy in order to be legally placed on the market, the procedures to evaluate the conformity of the devices as well as their classification. Following are some of the changes which may have an impact on manufactures and/or final users.

Changes introduced by the 2007/47/EC

• **INTENDED USER:** The duty to specify the intended user makes it compulsory for manufacturers of tailored medical devices to prepare clear and detailed instructions for their devices considering the end users skills and knowledge. This requirement is particularly important for devices intended for non-professional use.

• **CLINICAL EVALUATION:** The new directive emphasizes the need to provide clinical evidence for all devices. All devices are now in need of such data, including devices for Class I. This is undoubtedly the most important innovation of the entire Directive. Additionally, this imposes more stringent requirements for what constitutes "clinical trial" and calls for a stronger attention from the authorities. Annex X on clinical evaluations has been changed. Consequently, manufacturers must now analyze and review the clinical part during the planning stage to identify any problem that needs further investigation. Such control will be inserted in the document risk analysis at the design stage but also after the commercialization of the product in order to keep updated to the state of art all the technical data of the medical device. In fact, for a better demonstration on the

Substantial changes have been introduced on active implantable medical devices as well as on all other medical devices by the new EU directive 2007/47/EC, into force from October 11th 2007. According to the new directive, all Member States "shall apply [the transposition measures] from March 21st 2010". The consolidated Directive has become mandatory as of March 21st 2010, without any period of transition. Thus, in absence of any transitional provisions, medical devices placed on the market or put into service after March 21st, 2010 must meet the requirements of the revised directive. The introduction of these standards at national level emphasizes the need for companies operating within the Community to acquire adequate information to avoid mistakes on the interpretation of the regulations. The novelties introduced by the directive will have implications for manufacturers, Notified Bodies and national authorities.

compliance of the medical device, manufacturers are obliged to implement a procedure to review the production of the device even after its commercialization, with the duty to report to the authorities any accidents or withdrawal from the market. Clinical data may come from the following sources, to mention a few: a) clinical investigations carried out for the specific device b) clinical trials or other studies published in scientific literature relating to similar devices, where the equivalence of products must also be demonstrated c) Reports published on other clinical experiences related to the device or similar devices, where the equivalence of devices must be demonstrated.

• **STAND ALONE SOFTWARE:** Directive 2007/47/EC specifies that the software itself, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device must be considered a medical device. So the software must be validated according to the state of art, taking into account the principles of life cycle development, risk management, validation and verification. Harmonized standard EN IEC 62304:2006 "Medical device software - the processes of software life cycle" may be used to comply with new regulations. Moreover, software considered a medical device must be classified according to the classification rules set out in 93/42. Note that the stand-alone software is considered an active medical device (Annex IX, rule 1.4). For example, software packages that run on PC or Smartphone, which allow you to make diagnosis (telemedicine application) or involved in treatment plan (e.g. the simulation of surgical implants) are now considered active medical diagnosis or treatment. Therefore, as a stand-alone software it must be CE marked to indicate its compliance with the provisions of the Directive to enable them to move freely in the Community and be operated according to their destination.



• **ERGONOMIC DESIGN:** To ensure patient safety, ergonomic design is now considered an essential requirement of the medical device. The ergonomics of medical products is becoming the focal point of the development process. The harmonized standards EN 60601-1-6 and EN 62366:2008 can be used to demonstrate compliance with this requirement.

• **SINGLE USE:** Particular care must be taken to ensure that the reprocessing of medical devices does not endanger the health and safety of patients. Thus, for single-use devices, manufacturers must now provide all the information on known characteristics and technical factors that could pose a risk if the device were to be reused.

• **CONFORMITY ASSESSMENT:** Manufacturers of sterile medical devices and measurement can now enjoy greater flexibility in selecting the route to demonstrate compliance of their device. In fact, it has been introduced, specifically for them, the possibility of adopting a complete system of quality assurance in accordance with Annex II of Dir 93/42. This will be very useful for those manufacturers who are already certified under this Annex or for those that may also want to be included into this certification scheme accessories to their medical device that until recently needed to follow a different approach.

• **E-LABELLING:** The labelling of medical devices in the EU poses a challenge for producers that should provide instructions for use (IFU) in different languages. Currently, most IFU are provided in paper format, which can be very long. The term "e-label" refers to the possibility of using innovative means to provide IFU electronically. The new Directive 2007/47/EC gives to the manufacturer the possibility to provide information related to the medical device by other means. It could potentially allow to provide IFU in a CD or other electronic means, eliminating the various versions of paper now required.

• **DECLARATIONS OF CONFORMITY:** Manufacturers of medical devices are required to declare compliance with the directive of their product in a Declaration of Conformity. Declarations of conformity issued from March 21, 2010 are automatically referred to the revised Directive. From such date, manufacturers must be able to demonstrate compliance with all requirements of the revised Directive which apply to their product. If manufacturers have placed on the market or put into service products to meet the new requirements before March 21, 2010, they must have already declared that their Declaration of Conformity refers to Directive 93/42/EEC as amended by Directive 2007/47/EC. Otherwise, as in the case of declarations of conformity issued before October 10, 2007 (publication date of the amendment 2007/47), the statement should have been reprinted. When a notified body is involved in conformity assessment (e.g. peripheral class II or higher) it has to follow a similar procedure. A Practical Guide to EU-wide standards for the issuance of the new Declaration of Conformity can be found in the following document from the Commission on Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC of June 5, 2009.

The need to implement Directive 2007/47/EEC at national level within the European Community has enabled the EU Member States to introduce, with some limitations, further elements necessary to adapt the EU legislation to the specific national contexts, thus introducing different regulations in each country. It is therefore important that all companies intending to commercialize their products in the EU become aware of all the elements introduced in each single country within the community.

For further information and legal consultancy on CE certification:



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Implementation of the new EU Directive (2007/47/EC) in the Italian Legislation

The need to transpose Directive 2007/47/EEC (mandatory as of March 21st 2010) at national level within the European Community has enabled EU Member States to introduce, with some limitations, further elements to the specific national contexts.

The introduction of such regulations underlines the necessity for medical companies operating within the Community to acquire adequate information to avoid incurring risks.

This article will focus on the implementation of such directive in Italy, through the Legislative Decree 25 January 2010, no. 37, published in the Official Gazette no. 60 dated 13 March 2010. Given the rapid technical changes occurred in the design, production, use and safety of medical devices, this Decree is intended to make Italian legislation on medical devices more coherent.



As well as transposing the technical aspects of the new Directive, the Italian legislation has undergone adjustments on "supervision of accidents", "clinical trials", "publicity" and "penalty system".

In particular, rules governing the supervision of accidents present significant innovations: all withdrawals of medical devices from the market imposed by the Ministry of Health are under the responsibility and at the expenses of the manufacturer if the manufacturer has wrongly applied the technical regulations of the EU Directives or even if he has applied them correctly but they are not specific and complete for his type of production.

If the manufacturer fails to observe the obligation of withdrawal, it is considered a criminal offense. This subject is governed by Article 9 that replaced Article 10. The different types of accidents to be reported by health professionals (paragraphs 2 and 3) and manufacturer (paragraph 7) are included in the 1st paragraph of this article, while the methods of communication are currently defined in the Ministerial Decree 15.11.2005.

Lastly, the manufacturer must provide a method for assessing the experience acquired on his devices during commercialization (post-marketing follow-up, Annex II, paragraph 5 and Annex X, paragraph 1.1 c). In fact, the surveillance and supervision of accidents, operated by competent authorities of the Member States, are subsequent to the phase of commercialization and they occur either through random controls or reports from the parties.

Such method of subsequent controls on the entrance of devices into the market has led to the drafting of a policy that provides more specific requirements to keep records of the devices. For instance, attention was driven towards the inclusion of a deadline that represents a specific time limit required for keeping the documents, thus providing a base for the application of the penalty when rules are broken.

Furthermore, to ensure effective, proportionate and dissuasive force to sanctions, the cases for the use of special penal sanctions have been limited to two: non-disclosure of serious accidents and failure to comply with mandatory provisions of the competent authorities. The formula "unless the act constitutes a crime", was maintained to permit the application of any additional penalties and sanctions in cases of criminal offenses affecting constitutionally guaranteed interests such as health (e.g. Articles. 441, 582, 589, 590 of the Italian Penal Code).

In order to allow competent Italian authorities to run efficient and fast actions of monitoring and supervision to protect public health, two directions have been followed:

- updating of the rules on special measures for health monitoring and safeguard clause (Article 8-8-a and b, L. Decree N.507/92 - Articles. 7:13-ter of L. Decree no. 46/97);
- the provision of pecuniary sanctions for the subject responsible of improper or absent CE marking, alongside administrative measures restricting market entry as well as imposing the withdrawal of the product for evaluation (Article 9 L. Decree no. 507/92 - art. 17, Leg. n.46/97).

Over 90 sheets were drawn for the evaluation of both gravity and extent of the breach of regulations. Many factors were considered in preparing these sheets such as the territorial extension and potential duration of the infringement, the level of adverse effects, the potential illegal economic benefits obtained by the subject responsible, whether the guilt originated from intention or negligence, individual or collective punishable behavior.

Different categories of subjects potentially involved in the infringement were considered: from the manufacturer to the individual health professional (taking into account the degree of consciousness of the act, its consequences and the potential economic benefit that such persons might have drawn from the unlawful conduct).

Hence, five levels of indicators were identified for the violations contained in the text which, to ensure effective deterrence, have been associated to five levels of minimum amount of the penalty, setting the highest amount at six times the first.

The central subject in the regulation of medical devices, as it has been outlined for years at EU level, is the manufacturer/authorized representative.

Most of the obligations concern this category: manufacturers have to notify the Ministry of Health address and description of devices and they must provide all data necessary to identify these devices, along with label and instructions for use.

If the manufacturer is located outside the European Union, he must explicitly designate a single subject, natural or legal person established within the Union, who acts on behalf of and can be addressed to instead of the manufacturer. Manufacturers are also subject to sanctions ranging from EUR 500 to 128,400. Among the merely economic implementations, it is also included the payment, to be carried out by 30 April of every year, of a 5% contribution for self-assessment for promotional activities directed towards health care workers. (The obligation to pay is governed by 1st c. 409, Lett. d) of Act No. 266/05, as amended by Article. 1, c. 825, Lett. b), Law No. 296/06).

The contribution is borne by all "companies that produce or market medical devices in Italy, including in-vitro diagnostic medical devices and custom made devices". The rule applies to the promotion of a product by "doctors, health professionals, including executives of health institutions and pharmacists", if the product meets the definition of "medical device" and is labeled and marketed under the EU sector directives.

"The total expenditure borne in the previous year" is the basis of assessment for contribution. It includes specific "cost items" as by Technical Annex to the Ministerial Decree 23/04/2004 - relating to the pharmaceutical field, but to which this law explicitly refers to - excluding "net costs for the staff". Failure to pay leads to a penalty of EUR 7,500 to 45,000, besides the sum already due, increased by 5% for each month of delay.

The most relevant administrative penalties are those affecting subjects who place into the market or service medical devices without CE marking or attestation of conformity (both the manufacturer's declaration and any certificate issued by the Notified Body).

In such case, the penalty ranges from EUR 21,400 to EUR 128,400 for any subject placing in the market, selling or servicing non-compliant medical devices, as well as for the manufacturers of custom made devices that are non-compliant or without the declaration required in the relevant technical Annex.

These sanctions are aimed at protecting and ensuring the so-called "public confidence" in the regularity of CE marking. Just as serious are sanctions for the manufacturers/authorized representatives that mark a device inappropriately, as in the case of products falling outside the definition of the Decree, or unduly, because the product does not meet all essential requirements.

Medical devices not bearing CE marking are always subject to administrative seizure.

Source:

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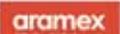
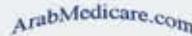
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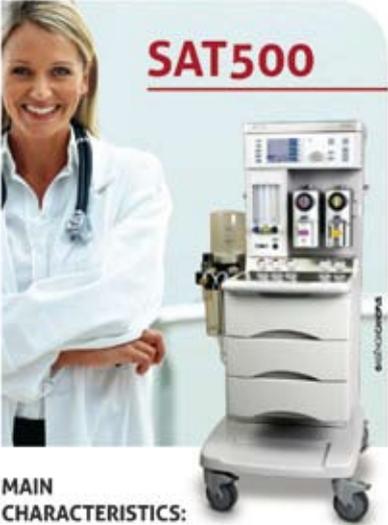
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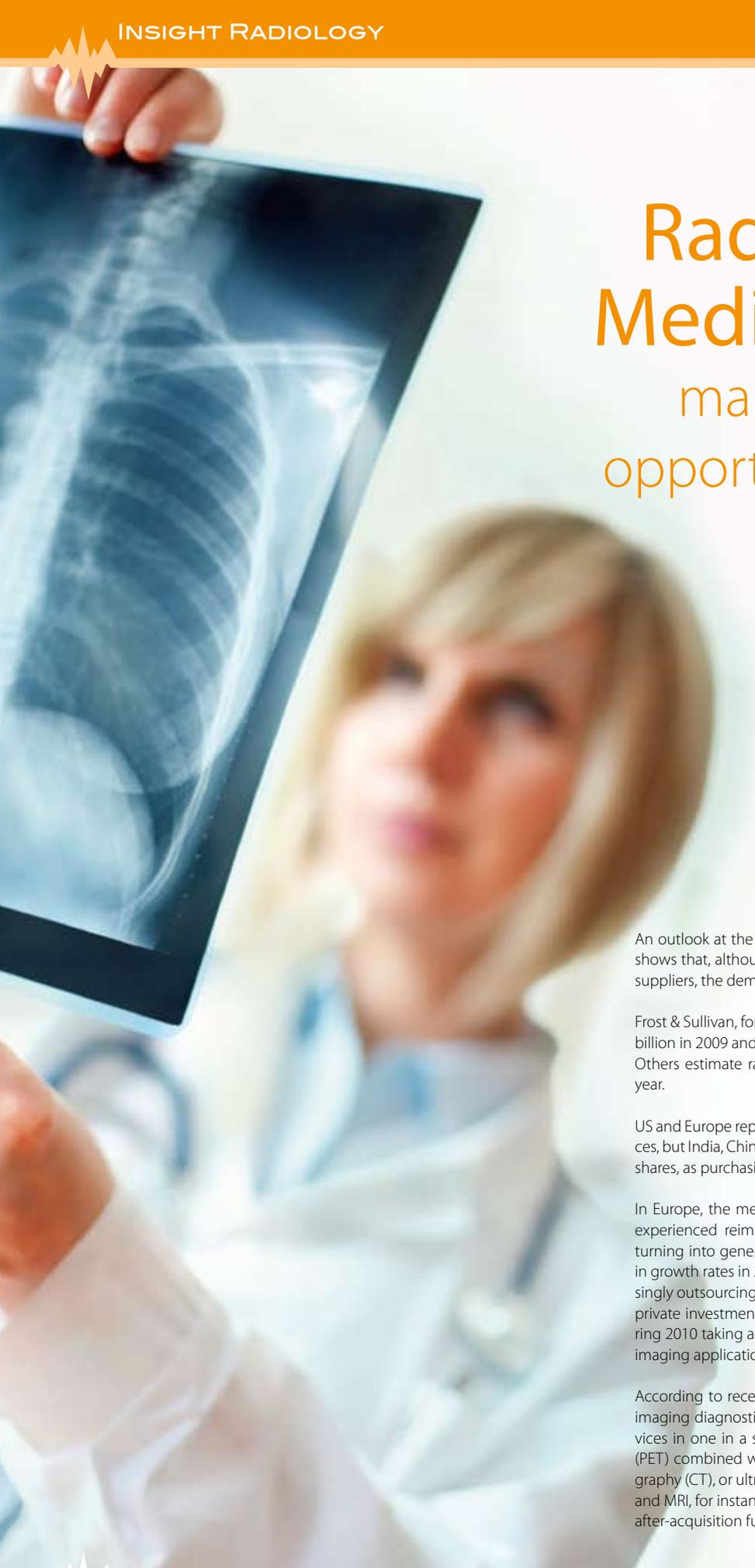
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Radiology and Medical Imaging: market trends and opportunities for growth

An outlook at the global market for diagnostic and medical imaging services shows that, although the economic downturn which also affected healthcare suppliers, the demand is still expected to maintain strong.

Frost & Sullivan, for instance, estimated revenues from medical imaging at \$5.7 billion in 2009 and forecasts growth to reach \$6.5 billion in 2012. Others estimate raise the expected revenues at over \$9 billion by the same year.

US and Europe represent the largest market for radiology equipment and services, but India, China and the Asia-Pacific region are also gaining relevant market shares, as purchasing power and availability of healthcare services improve.

In Europe, the medical imaging market has felt the effects of recession as it experienced reimbursement constraints and lower budgets for healthcare, turning into general delays in renewal of radiology equipment and a decline in growth rates in 2008 and 2009. On the other hand, with government increasingly outsourcing imaging diagnostic services to private centers and growing private investment, the imaging sector has a good potential for recovery during 2010 taking advantage of the fast development of new technologies and imaging applications, as well as of integration between radiology and IT.

According to recent releases anticipating trends on display at MEDICA 2010, imaging diagnostics is focusing on hybrid procedures that combine two devices in one in a single examination, such as positron emission tomography (PET) combined with magnetic resonance imaging (MRI) or computer tomography (CT), or ultrasound combined with endoscopy. The combination of PET and MRI, for instance, would allow simultaneous image acquisition rather than after-acquisition fusion, as is the case with PET-CT.

Endosonography (or Endoscopic Ultrasound, EUS) allows ultrasound to contact organs and tissues from the inside by means of an endoscope. The aim is twofold: to obtain more accurate information by reducing examination time and stress for the patient. Largest amounts of data obtained by innovative procedures will require further investments in technologies for data storage and analysis.

A closer look at single market segments such as digital radiography, CT and 3D imaging systems, mammography, MRI and ultrasound shows that Europe is in a leading position in the global radiology market.

According to figures reported by the European Committee of the Radiological, Electromedical & Healthcare IT Industry, in 2008 there were 23.6 CT systems per million inhabitants in Western Europe. Higher density (over 30 systems per million) were registered in Austria, Switzerland, Norway, Germany and Italy, while lower than 20 systems/million population densities were observed in France, Netherlands and the UK. The percentage of systems over 5 year old increased from 38% in 2006 to 40% in 2008.

In Central and Eastern Europe, the average density amounted to 8.2 systems/million population, with lowest densities in Bulgaria, Romania and Ukraine, while Russia has on average 8 systems/million inhabitants.

The 3D medical imaging market is forecasted to grow by \$3.9 billion by 2012, boosted by technological advances in visualization techniques and the need to reduce time for image processing and interpretation.

Picture archiving and communication systems (PACS) driven by radiology information system (RIS) are among the most interesting and growing segments,

as part of the general growing trend observed in healthcare IT services. Frost & Sullivan reported valued the European RIS/PACS market in Europe at \$679.4 million in 2009 and forecasted that it will reach \$1,353.3 million in 2016, but according to the report, penetration in European hospitals is uneven, with a rate of 80% for PACS and 41% for RIS, due to the more difficult implementation and training connected to RIS and concern it arises over data migration and security. It is however expected that more hospitals will invest in modern RIS systems to drive PACS installations, and purchase it from the same vendor as a single package.

As regards the European Mammography market, screening programmes implemented by governments in many European countries drive the demand, and even though in some countries analogue mammography systems are still more common, the demand is declining as one of the main trends is the shift towards full-field digital mammography (FFDM) systems.

As far as sales are concerned, 92.5% of revenues comes from digital systems while the market share of the analogue mammography systems is estimated at about 7.5%. Big players such as GE, Siemens, Philips, Toshiba, Hologic dominate in this sector but price-based competition will come from the increasing participation of smaller companies. In some countries, yet, market expansion is still hampered by local policies, delays in public screening programmes or insufficient budget allocations. Mobile screening units play a significant role in covering remote areas, as telemammography allows the transmission of digital mammograms for expert consultation. Mobile units are also being used in hospitals in emergency rooms and operation theatres. Higher awareness and broader screening programmes can boost the market for mobile mammography units.

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Magnetic resonance imaging (MRI) and ultrasound are among the main imaging systems offering good visualization of internal organs without using radiation. In 2008, MRI's market revenues in Europe were valued at \$858 million, forecasted to reach \$996.3 million in 2012. About 46% of all installed MRI systems exceed 5 years of age. COCIR figures on MRI density across Europe show that, while in Western Europe there were on average 15.6 MRI systems per million inhabitants, with the figure raising at over 20 in Switzerland, Norway, Denmark, Germany and Austria, average density in Central and Eastern Europe is 2.6 systems/million inhabitants.

Ultrasound market revenues reached \$371 million in 2008, with projected growth to \$438 million in 2015.

Frost & Sullivan describes the European market for ultrasound systems as primarily a replacement market, given the high degree of saturation. However, therapeutic and contrast-enhanced ultrasound are presenting interesting perspectives. For example, high-intensity focused ultrasound (HIFU), or high energy ultrasound, concentrates the waves to bring the temperature up to 90°C in order to target and destroy tumors without damaging surrounding tissues. Its application in urology and gynecology is already widespread, but high energy ultrasound is also being used in bone tumors treatments and in aesthetic procedures such as removal of subcutaneous fat cells as an alternative to liposuction.

Sources

European Committee of the Radiological, Electromedical & Healthcare IT Industry (COCIR) – www.cocir.org

European Medical Technology Industry – www.eucomed.org

Messe Düsseldorf GmbH – www.messe-duesseldorf.de // www.medica.de

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Imaging diagnostic market in Poland and Hungary: boom or bust?

According to the newest report published by PMR Publications "Imaging diagnostics market in Central Europe" the Eastern European market for imaging diagnostics is young and considered to be in its growth phase. Poland and Hungary comprise very attractive countries of Eastern Europe swiftly embracing the healthcare model espoused by Western Europe. However, political instability and infancy of the democratic system in these countries remain the stumbling blocks for the imaging diagnostics market. The unpredictable and cyclical nature of centralised investment resulting from political instability is a deterrent, leaving the imaging diagnostic market in need of some private investment.

Private sector has started to assert itself in Poland and Hungary, with private diagnostic centres becoming an increasingly regular feature of the healthcare landscape. There are some optimistic signs indicating that Polish and Hungarian systems are on the right track including tackling the problem of over-provision of hospitals and hospital beds by reducing the lengths of stay and shifting the appropriate treatments to the primary sector. The cost savings realised by combating unnecessary infrastructure are channelled towards the modernisation of hospitals, meaning newest modalities in medical imaging will now be supported.

Another source of optimism with regard to funding lies with the prospect of funds from the EU structural funds for Hungary, Poland, Czech Republic and the Baltic States for the years 2007-2013. Unlike Western Europe, where workflow enhancements and technical features of a modality are important, Eastern Europe diagnostics imaging market is primarily driven by price sensitivity, not features. The main modality vendors are thus compelled to offer competitive prices in the face of local competition, causing severe erosions of profit margins.

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Imaging diagnostic market in Poland

Poland is one of the biggest healthcare markets and the most developed and technologically advanced countries in the Eastern European region. Public hospitals purchase their medical equipment through the competitive bidding process and private clinics prefer buying the most advanced modalities from any source they prefer. Equipment purchases and maintenance procedures at public hospitals are funded by the government or by medical foundations, which also raise money to purchase equipments for hospitals. Poland is amongst the world's top 20 markets and is on the path of decentralisation. The country has a lower healthcare expenditure in terms of GDP as compared to Hungary. Hospitals and the government face an increasing pressure to curb healthcare expenditure.

Imaging diagnostic market in Hungary

The country is currently shifting from the centralised system to a decentralised model by privatising healthcare facilities and encouraging private investment. Continued economic development and technological progress will fuel demand for improved and advanced medical imaging modalities, resulting in imaging diagnostics market growth. However, the Hungarian healthcare system is fraught with certain problems such as excessive number of doctors, lack of training to physicians, inadequate infrastructure and others.

Perspectives

The growing medical imaging modalities market can be attributed to the increasing number of procedures involving diagnostic imaging. The well-established and key modalities that form the major market sectors in Eastern Europe are: X-ray, ultrasound, CT and MRI.

The most common class of procedures performed are radiography, followed by ultrasound, CT and MRI. The transition from film to digital imaging and replacement of old radiography systems will remain the main drivers for the X-ray systems market. Ultrasound market, being the most preferred modality and less prone to cyclical investment, is expected to show high growth especially in the private sector. New 4D ultrasound systems, laptop or hand held devices for point of care testing and improved contrast media will contribute to the growth of the market. CT scanning is one of the most promising areas in the medical diagnostics market in Eastern Europe as the old single and dual slice CT machines are anticipated to be replaced. Favourable reimbursement and better return on investment prospects have made healthcare institutions inclined towards opting for CT machines, thus providing the necessary impetus for market growth. MRI, the modality positioned highest in the value chain, is also expected to show high growth due to the burgeoning private sector. With an increasing number of MRI procedures and with eroding prices of MRI hardware, the market is expected to achieve high growth rates in the forecast period.

Will the imaging diagnostics market emerge out of the market slump?

Major modality vendors are looking to expand into the emerging countries of Eastern Europe like Poland and Hungary. Government sponsored healthcare programs are now resorting to the outsourcing of imaging diagnostics to private imaging centres. Most public hospitals are looking towards private finance companies to enable them to invest in medical imaging modalities. As the utilisation rises and healthcare gets reformed, demand for high tech imaging will create a need for MRI scanners and CT. The future seems promising as the new technological developments take place and the nations see new reimbursements rates pertaining to imaging equipment from the start of 2010.

A peek into the trends that would sell

A steady increase in demand for quality medical imaging services is expected to boost the medical imaging market in the next decade. Technological integration or development of hybrid modalities like PET and MRI will help the diagnostics imaging market to combat competition and provide comprehensive diagnosis. Molecular imaging is one of the most exciting technological advances to come in imaging and it is the number one focus of most of the tier #1 vendors. Incorporating PACS to store data (3D and 4D images) obtained from the imaging modalities will pave way for another trend in the imaging diagnostics market. Innovations like higher resolution and digitisation initiatives are spurring growth in the imaging diagnostics market in Poland and Hungary.

Global medical imaging vendors are now also opting for strategies such as leasing, product life cycle management services, rental and financing options to boost revenues and maintain sustainability. Also, a lot of their growth strategies are focused towards post sales servicing, support and innovative consulting services for hospitals.

Recommendations for modality vendors

- Vendors with financing capabilities are likely to attract end users and have a better scope in the Eastern European market. GE Healthcare is one of the companies to set up its own financing wing, making it easy for healthcare organisations to acquire high-end modalities like MRI.

- Tie up with local distributors to broaden the company's product portfolio. The Eastern European market, being an extremely price sensitive market, demands low-priced equipment. In order to facilitate high penetration, brand building and make end users receptive towards high-end products, low priced-vendors will allow major participants to reinforce their market presence. Tying up with local participants will help major vendors to extend towards the low-end spectrum and fill any gap in a company's product portfolio.



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- Hospitals in Eastern Europe lack surplus capital, which has resulted in reliance on old equipments. Vendors are required to focus on competent pricing policies and quality of the medical imaging modalities. Offering upgraded solutions to cost-conscious end users and better payment options to the private sector help companies to gain end-user confidence. Companies which offer additional features such as software and hardware upgrades, free maintenance and replacement of the imaging equipment are able to attract customers.

- An efficient cost-distribution network will help companies achieve more sales and help to cut down the costs associated with customer service support. A distributor typically handles a lot of products of different brands, it is thus very important for the vendor to establish a strong relationship with the distributor. A distribution network, if established appropriately, will encourage distributors to focus on products of a particular vendor and provide services, which has similar qualities to direct sales.

The article is based on the report "Imaging diagnostics market in Central Europe 2010. Development forecasts for 2010-2012" published by PMR Publications in August 2010.

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PMR Publications (www.pmrpublications.com), a division of PMR, provides reliable market intelligence for business professionals interested in Central and Eastern European countries. Publications by PMR provide analysis of the business climate in the region, in particular the pharmaceutical sectors. PMR Publications offers both free and paid subscription newsletters, internet news portals, and in-depth reports.



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The British Healthcare Sector

Strengths and Opportunities



An acknowledged centre of excellence

The UK healthcare sector has developed into one of the world's most diverse and dynamic marketplaces, boasting a high number of major companies and a wealth of SMEs.

As in several countries, the organisation of health services in the UK is quite complex and it has undergone radical changes. Over the last few years, the budget for the healthcare system has strongly increased to face a modernisation programme aimed at providing British citizens with modern, advanced and reliable health services.

Health in the UK is organised on a public basis and provided by the National Health Service (NHS), which aims to provide a comprehensive healthcare system. Founded in 1948, the NHS is the world's largest publicly funded healthcare system offering free health services to British residents on the basis of clinical need. According to the most recent data, on average the NHS deals with one million patients every 36 hours.

Acknowledged globally as a centre of excellence, the NHS accounts for some 85% of the UK's healthcare provision, with the private sector covering the remainder of the market. With a skilled and dedicated workforce of more than 1.5 million and a patient pool in excess of 60 million, the NHS is one of the largest purchasers of life science products in the world and therefore offers a potentially lucrative business customer for any company active in the healthcare industry.

Although funded centrally, NHS services in England, Scotland and Wales are managed separately. The UK Department of Health sets the standards of healthcare. In England it also controls the 10 Strategic Health Authorities created in 2002 to manage the NHS locally and oversee the Primary Care Trusts, free standing NHS bodies responsible for delivering healthcare to their local areas. In addition to these bodies there are a several other structures responsible for delivering health services to citizens such as the Acute Trusts (whose task is to manage hospitals), NHS foundation trusts (a new type of NHS hospitals run by public staff whose services are tailored to the needs of local population), NHS care trusts (providing care in both health and social fields), ambulance trusts (managing and providing emergency access to healthcare).

The British NHS actively cooperates with the industry to deliver new products and improve health services to British patients. As a matter of fact the British life science sector (which comprehends biotechnology, healthcare and pharmaceutical industry sectors) is one of the most active in the world. To give a few numbers: 35% of all European biopharmaceutical trials take place in the UK, 10% of the world pharmaceutical R&D is directed in the UK where the world's top six universities are also located.

The UK pharmaceutical sector employs some 67,000 people, working in around 600 companies with a turnover (according to 2009 data) of £ 15.6 billion. In 2008 medicines originated in the UK accounted for 16% of global pharmaceutical sales. The UK medical technology sector has over 2,700 companies and employs 52,000 people. Its activity is present in every region of the UK. Its largest segments by turnover are: wound care management, in-vitro diagnostics, orthopaedic devices and single use technology.

The medical biotechnology sector in the UK is driven by innovation with 86% of all companies engaged in research and development. It is one of most developed medical biotechnology sectors in Europe with a balance of young and established businesses. These are supported by a network of specialist suppliers employing 56% of the sector workforce. The sector has developed a manufacturing infrastructure with 26% of companies investing in this capability. Of companies developing new therapies, the largest segments in terms of turnover and employment are small molecules, antibodies and therapeutic proteins.

Overall, exceptional science and skills, unique health system, trade links and excellent communication make the UK the ideal base for global business in the healthcare sector. Market opportunities for innovative foreign companies will continue to remain strong, particularly in areas such as healthcare and medical technologies. The UK is committed to continuing its support of highly innovative activity in the life sciences sector.

UK Trade & Investment (UKTI) is the British government organisation which supports British companies in their overseas trade activities. UKTI has an extensive network of staff and offices both in the UK and overseas in Embassies, Consulates and High commissions offering tailored services to British companies to access overseas markets and expand business internationally. UKTI offices also offer services and advice to overseas companies interested in investing in the UK.

The UKTI network in Italy is headed by Dr. Laurence Bristow-Smith, HM Consul General and Director General for Trade and Investment. The team operates from Milan, Rome and Naples.

UKTI staff in the UK and overseas is happy to answer enquiries and provide additional information about UKTI services available to British and overseas companies. Please visit www.ukti.gov.uk and www.ukintaly.fco.gov.uk or contact: milancommercialenquiries@fco.gov.uk.

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Sources: UK Trade & Investment; Department for Business, Innovation & Skills.

Developing healthcare sectors and future investment opportunities

How do you improve the delivery of healthcare, and in the process create a sustainable programme that allows Primary Care Trusts and Local Authorities to invest against a strategic plan for medium and small buildings, to deliver new models of health and social care? Taking on this challenge would require skills found in the public and private sectors, requiring them to come together to form a partnership that would plan, develop and maintain the estate required to enable public services to be delivered for the benefit of the communities they serve.

Tasked with delivering this new strategic approach to primary and social care investment the Department of Health (DH) recognised the need to create a new organisation able to identify with the needs of the healthcare community at its core, but have the financial expertise to access and attract the funding necessary to make the primary care vision set out in the NHS Plan a reality. In response to this challenge the DH joined with Partnerships UK (PUK) to create Partnerships for Health (PfH), later to become Community Health Partnerships (CHP).

CHP's initial focus was to encourage, guide and support the public private partnerships to be known as Local Improvement Finance Trusts (LIFT). CHP introduced structures that facilitated the introduction of the LIFT programme and created guidelines around LIFT operations, creating the foundations for long-term value adding vehicles for change.

Over the last 9 years CHP have created a sector that has seen £2 billion of investment in primary and social care infrastructure. They have facilitated the creation of 49 LIFT Companies across England, directly invested in each company and helped to create thousands of jobs.

In supporting and developing the LIFT programme CHP has taken on a number of roles.

- Informed and educated, providing expert procurement support to enable public sector partners to make informed decisions.
- Promoted the advantages of the LIFT programme through knowledge transfer, awards, sponsorship, workshops and best practice.
- Developed, adapted and aligned LIFT documentation to maintain a focus on value, and created toolkits and training support for national policies.
- Championed the ethos of LIFT, supporting the public sector partner to drive the LIFT Company towards delivering best value outcomes that deliver change to local communities.





As LIFT Innovation Programme and Knowledge Transfer Manager Graham Spence, who was one of the speakers at the seminar organised by UK Trade & Investment at Exposanità Bologna in May 2010, points out that the true value of LIFT lies in the successful partnerships between the public and private sectors. CHP have played a key role in driving this value forward, facilitating its growth through investment, research, communications and training. CHP has demonstrated a remarkable ability to identify and deliver solutions in the creation of a programme worth more than £2 billion in just 9 years. The LIFT programme has achieved a balance between the need to attract and retain investment from the private sector, whilst delivering the life changing services and facilities that lie at the heart of the health and social care agenda.

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The Medical Market for Healthcare Innovation in England's Northwest The NHS Innovation Gateway

Adrian Warner, Business Development Manager, works in TrusTECH's business consultancy service. He was one of the speakers at the seminar organised in Bologna by UK Trade & Investment at Exposanità in May 2010. Here he explains how the NHS is going to have to rely on efficiencies through innovation, and how this could open up the Healthcare market in the UK.

Background

Healthcare Innovation will play a bigger, more important role in tomorrow's National Health Service in England.

The McKinsey report (March 2009) helped focus on cost savings of £20bn over a 3-5 year period and spoke in terms of recurrent potential savings in: acute provider productivity (9-14%); non-acute provider productivity (8-12%); supply chain (8-13%); enhancing self-care and chronic disease management (10-13%). The current white paper on the future of England's Health Service "Liberating the NHS" (July 2010) restates the need for £20bn efficiency savings and reducing NHS management costs by at least 45% by 2014.

The existing Quality, Innovation, Productivity and Prevention (QIPP) initiative will continue with even greater urgency and is identifying how efficiencies can be driven and services redesigned to achieve the twin aims of improved quality and efficiency.

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England's Northwest

The North West of England is home to 7 million people and in this region there are 65 NHS organisations ("Trusts") employing over 216,000 staff and spending in excess of £4 billion on non-pay per annum.

The North West Biomedical sector has an annual turnover of around £6.1 billion and employs over 20,000 people in core activities related to the biomedical sector but many more find employment in "B to B" companies providing specialist goods and services to the core companies directly engaged in the biomedical sector, for example manufacturing components, machine tools and equipment supplying raw materials or distribution and packaging.

Around 164 core companies are involved in medical research and development, manufacturing and service in the biomedical area with roughly another 200 companies offering specialist supplies to the sector.

These companies benefit the local economy in two ways, by generating revenue and securing inward investment for the region. It has been estimated that the total gross value added for the biomedical sector in the Northwest region was £1.59 billion in 2008 and over £312 million of investment had been raised by Northwest companies operating in the sector between 2002 and 2008.

Healthcare Innovation in the Northwest

The North West is an exemplar region for innovation in healthcare. Examples of the region's rich biomedical history include: Sir John Charnley (Wrightington) pioneering human joint replacement in the early 1960's; Lilly (Speke, Liverpool) being the first commercial manufacturer of a recombinant DNA product (insulin) in 1982; Louise Brown, the world's first test tube baby born (Oldham) in 1987; Medeva (Speke, Liverpool) being the first company to take a biologic product (Hepacare™) through European regulatory system in 2007.

Currently many front-line innovations are flourishing across the region, supported by both the NHS Innovation Hub for the North West (TrusTECH, www.trustech.org.uk), and the NHS Technology Adoption Centre (NTAC, www.technologyadoptioncentre.nhs.uk). These include:

- Reducing length of hospital stay and adverse events using patient management/ early warning

scoring software – Evaluated by TrusTECH and now adopted into NHS Trust;

- Evaluating new technologies for combating Health Care Associated Infections (HCAIs) – TrusTECH ran the national "Smart Solutions for HCAI" programme of work for the Department of Health;
- TrusTECH facilitated the evaluation of a novel non-toxic biocidal cleaning agent leading to its adoption into NHS Trust to help combat MRSA and C-difficile;
- TrusTECH helped to develop a novel tibial fixation device for anterior cruciate ligament (ACL) repairs to reduce the failure rate of this common orthopaedic procedure;

- NTAC supported the implementation of oesophageal Doppler monitoring during major surgery to optimise fluid management, which reduces the risk of post operative complications resulting in shorter hospital stays;

- NTAC has led an implementation project to improve access to insulin pump therapy to improve the management of diabetes reducing the risk of emergency admissions and long term complications;

- NTAC led the introduction of a new non-invasive technique for assessing the need for invasive diagnostics and surgery due to bladder outflow obstruction;

- NTAC has supported the implementation of a new type of subrapubic catheterisation technique using a guide wire technique improving safety and avoiding the requirement for a general anaesthetic;

With connections across Industry, Academic and Healthcare Sectors, TrusTECH is central to the innovation landscape integrating the needs of the NHS with innovations in the healthcare industry. The NHS Innovation Gateway, operated by TrusTECH, provides this support interface and provides continuity through the innovation process from initial idea to adoption.

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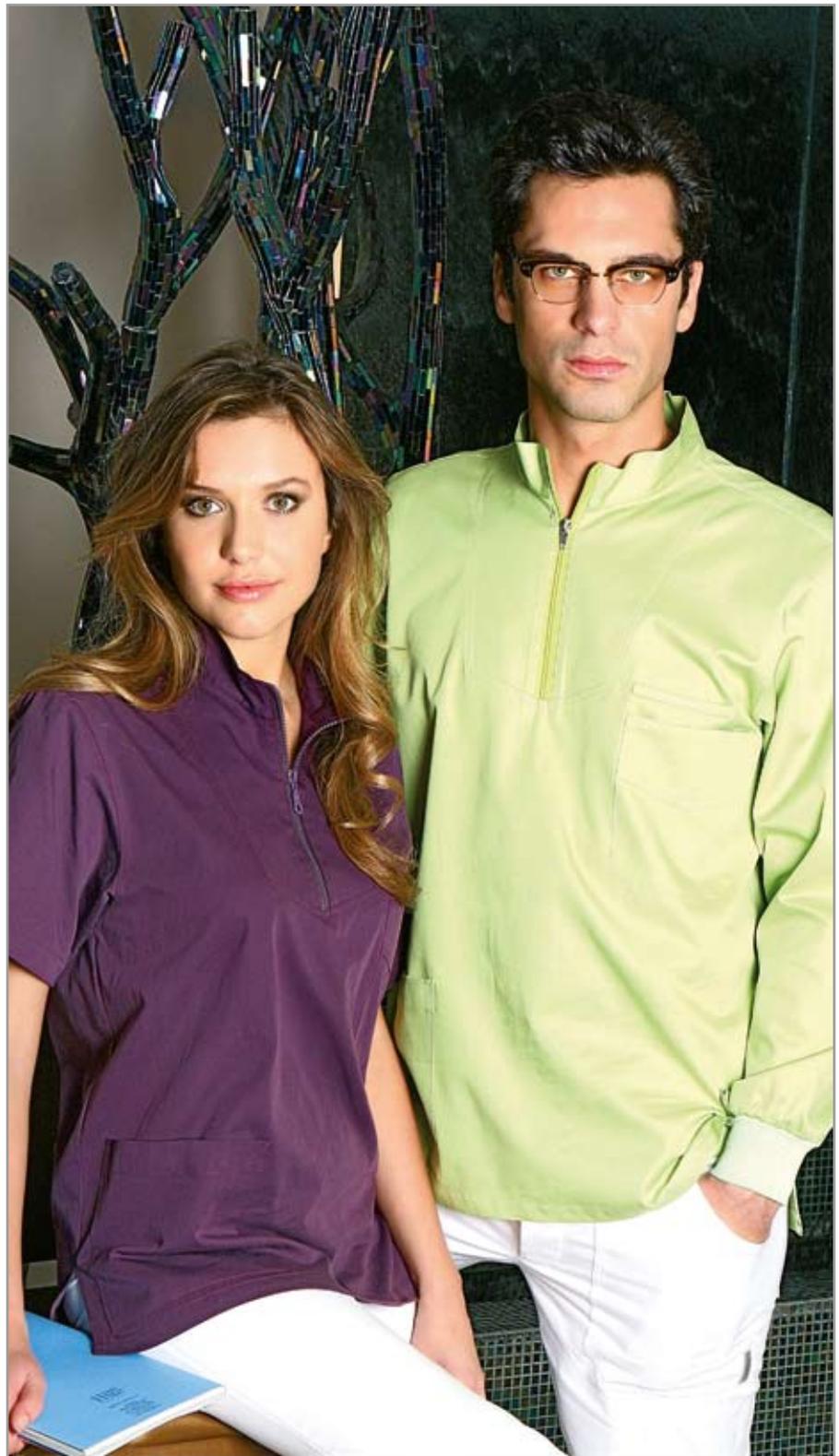
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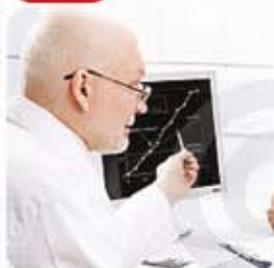
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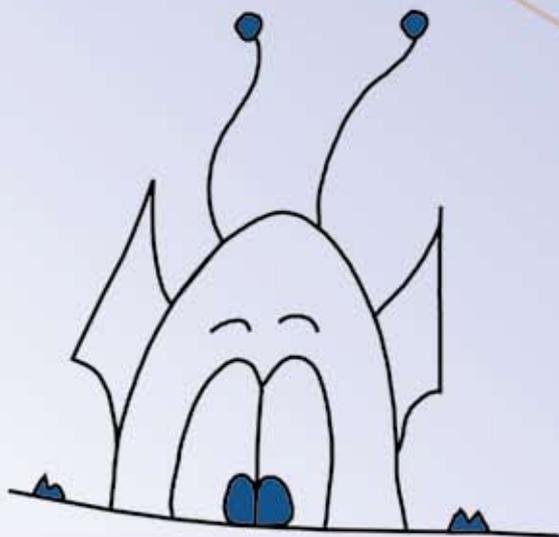
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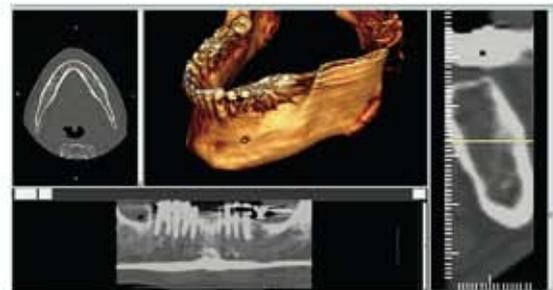
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