

# MEDICAL DEVICES MARKET IN ROMANIA

a DEMO sector brief by

FRD Center



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*Sources consulted for this report: business mass media, the companies, official sources*

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## **Imports of medical devices**

According to Espicom, approximately 90% of the medical equipment in Romania is imported.

The imports of the medical instruments and appliances in Romania in 2013 have recorded the following values:

- electrocardiographs: approx. 1.9 million EUR
- ultrasonic scanning apparatus: approx. 11 million EUR
- magnetic resonance imaging apparatus: approx. 8.8 million EUR (y/y increase of some 4%)
- scintigraphic apparatus: approx. 0.3 million EUR
- other monitoring apparatus: approx. 7.2 million EUR
- ultraviolet or infra-red ray apparatus: approx. 0.4 million EUR
- syringes (with or without needles): approx. 9.3 million EUR (y/y growth of some 27%)
- tubular metal needles and needles for sutures: approx. 2.8 million EUR (up by approx. 3% compared to 2012)
- other ophthalmic instruments and appliances: approx. 7 million EUR (y/y increase of some 26%)

The Romanian imports of mechano-therapy appliances, massage apparatus and psychological aptitude-testing apparatus have recorded approximately 8.7 million EUR in 2013. Furthermore, the imports of the ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus have reached some 5.9 million EUR in 2013, up by approximately 12% compared to the previous year.

The imports of the orthopaedic appliances and artificial parts of the body in Romania in 2013 have recorded the following values:

- orthopaedic appliances, splints and other fracture appliances: approx. 6.7 million EUR (up by some 17% compared to 2012)
- artificial joints: approx. 7.2 million EUR (y/y increase of approx. 28%)
- other prostheses (including ocular prostheses): approx. 16.5 million EUR (up by some 12% compared to the previous year)
- hearing aids, excluding parts and accessories: approx. 5.2 million EUR (y/y growth of some 34%)
- pacemakers for stimulating heart muscles, excluding parts and accessories: approx. 2.5 million EUR

## Purchasing of medical devices

The public hospitals in Romania organise tenders in order to acquire medical devices and equipment. In such tenders, the participants are usually local firms: importer-distributors and representatives of foreign brands.

Some examples of recent tenders organised in 2014 are briefly presented below:

- The Constanta County Emergency Hospital has organised a tender in order to acquire operating room devices and instruments and to receive repair and maintenance services. The winner of the tender has been the importer-distributor Sterimed Com and the contact has exceeded seven million EUR.
- The Oltenita Municipal Hospital has organised a tender to purchase physiotherapy devices, dermatology apparatus and instruments, surgical lamps, anaesthesia and resuscitation devices.
- The Obstetrics-Gynaecology Clinic Hospital “Cuza Voda” in Iasi has organised a tender for acquiring medical devices. The winner of the tender has been the importer-distributor Gadagroup Romania and the value of the contact has recorded 0.3 million EUR.
- The Regional Institute of Gastroenterology and Hepatology “Prof. Dr. Octavian Fodor” Cluj has organised a tender for the purchasing of monitors of hemodynamic parameters and infusion pumps.
- The Department of Public Health in Iasi has organised a tender in order to purchase medical devices for the Hematopoietic Stem Cell Transplant Unit of the Regional Institute of Oncology Iasi and to receive repair and maintenance services. The contact has registered 0.9 million EUR and the winner of the tender has been the importer-distributor Mediclim.
- The Bucharest Clinical Emergency Hospital has organised a tender with the purpose to acquire supplies for angiography and interventional radiology laboratory (stents, diagnostic catheters, introductory sets, angiography connectors, metal spirals etc).

## Sector focus: Importer-distributors of cardiovascular devices

Some of the main importer-distributors of cardiovascular devices in Romania are: Soft Medica, Gemedica, Tehno Electro Medical Company, Sante International etc.

Some of the most dynamic importer-distributors of coronary stents in Romania are:

- Established in 2009, **Medical Devices & Diagnostics** imports and distributes coronary stents, balloon dilatation catheters, guiding catheters, diagnostic catheters, dialysis catheters, drainage catheters, ablation catheters, therapeutic infusion systems, coronary guide wires, hemostasis valves, pacemakers, CRT devices etc. The company imports products manufactured by Abbott Vascular, Merit Medical and Biotronik. Medical Devices & Diagnostics has recorded a net

turnover of almost 6 million EUR in 2013, up by 10% compared to 2012. The company has over 10 employees.

- Set up in 2006, AGP Invest International imports and distributes coronary stents, stent grafts, nasal dilators, orthopaedic belts, orthoses, surgical gowns, surgery staplers etc. The products are manufactured by Hexacath, Iberhospitex, InSitu Technology, Pharmacure Health Care, Advan etc. In 2013, AGP Invest International has registered a net turnover of over 0.1 million EUR, up by 46% compared to the previous year.
- Daco Medical Technologies has been established in 2011. The company imports and distributes coronary stents, peripheral stents, catheters, urology devices and accessories, laparoscopic surgery devices and accessories, vascular medical devices, reagents, endoscopy accessories, prostheses etc. Some brands distributed by the company are: Translumina, Andramed, CardioMed, MSM, Mahe Medical, Medi Surg, Asid Bonz, FIAB, Ovesco, Biohit, Viasonix, INION, Histolab etc. Daco Medical Technologies has reached a net turnover of 0.1 million EUR in 2013, up by over 80% compared to 2012.

### **Legislation, certification required**

The core legal framework operating in Romania consists of three EU directives: Directive 90/385/EEC regarding active implantable medical devices, Directive 93/42/EEC regarding medical devices and Directive 98/79/EC regarding in vitro diagnostic medical devices. The aim of the EU directives is to ensure a high level of protection of human health and safety.

In order to comply with the EU requirements, the Romanian Parliament has adopted the Law 95/2006 on health care reform, with subsequent amendments. The law is the regulatory framework for the inspection of the medical devices and of the marketing and distribution activities of the medical devices and the related services.

The Competent Authority in the sector of medical devices in Romania is the National Agency for Medicines and Medical Devices (ANMMDM), a public institution subordinated to the Ministry of Health. The assessment of the suppliers of medical devices is the responsibility of the Agency for Health Assessment and Quality, subordinated to the Ministry of Health. The medical devices sold in the EU, therefore also in Romania, must have the CE marking.

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**FRD Center Market Entry Services**  
[www.market-entry.ro](http://www.market-entry.ro)

**Contact: Jackie Bojor, Director**  
[europa@frdcenter.ro](mailto:europa@frdcenter.ro)  
+4021 4111459