The medical device market in Poland

Plus a list of medical devices currently registered in Poland

PMR PUBLICATIONS

Launching medical devices in Poland

Introduction

Since Poland joined the EU in May 2004 the level of interest in the market for medical devices has expanded considerably. There are two fundamental questions which any international medical device manufacturer has to ask:

1. Is there a market for their product in Poland, either in the state funded sector, where crumbling buildings and an atmosphere of financial crisis often conceal surprisingly modern operating theatres and equipment, or in the small but growing private sector?
2. What has to be done to gain regulatory approval? The possibility of using existing European Union registrations to gain approvals in Poland is obviously of great interest and the good news is that Poland does recognize EU certification for two categories of medical devices. The less good news is that a number of hard to interpret forms may need to be completed (in Polish) and submitted to the relevant authorities in order to take advantage of the mutual recognition provisions. The status of each individual medical device (and whether documentation needs to be filed) should be carefully reviewed in each case. The situation with respect to enforcement of EU mutual recognition laws is far from clear.

Is there a market?

In 2002 there were 739 general hospitals in Poland of which 678 were state-owned and the remaining 61 were either privately-owned or controlled by non-governmental entities. Additionally, the Ministry of National Defense operates 24 hospitals and the Ministry of Internal Affairs and Administration operates 29 such institutions. There were 3 more hospitals altogether in comparison to 2001, but this was due to the fact that 16 new private hospitals started operations while 13 old state-owned hospitals folded. This seems to reflect a growing demand for higher quality medical services as most state-owned hospitals are huge complexes,

often with out-of-date and worn-out equipment and located in old, damaged buildings, some built more than a hundred years ago.

As far as the usage of medical devices goes, one recent study showed that 85% of medical devices available in 49 public hospitals in the Malopolskie voivodship (area around Cracow) were in a "bad" or "unsatisfactory" condition and there was not a single hospital whose overall medical devices were in a condition described as "very good". Simultaneously 72% of technical infrastructure was described as at least "worrying". There is no reason to expect that the state of medical infrastructure of Polish hospitals is much better in the remaining 15 administrative regions across the country.

Other than hospitals there are also nearly 16,000 clinics where patients come to consult a doctor or have minor treatments. These medical units (of which 76% are privately owned) vary in size and most of them are staffed by just a few persons. The medical devices used in private clinics are often quite good while their state-run counterparts often use older equipment dating back to the 1960's or 1970's, is highly damaged and even defective due to overuse and poor servicing. However, higher priced equipment is often only available in the state funded hospitals (being beyond the reach of most private clinics). Private clinics form an unofficial gateway to provide queue busting access to the most expensive medical kit in the better funded hospitals in any given town or region. The patient pays 50-100 zloty (5-10 Euros) to see a specialist in a private clinic, is told (if necessary) to show up in a state hospital when that specialist is on duty, call the doctor on his mobile phone, who then fixes the second investigation on expensive equipment paid for by the taxpayer that is not available in the private clinic.

Poland will have to upgrade its health care system as its population ages. This together with the relatively poor health of many of its inhabitants, creates a reasonable expectation of sustained and increasing demand for many types of medical devices. In some cases European Union funds which Poland (and other new member states) are now entitled to, may be available to subsidize some of the costs.

Altogether, this means that Poland is likely to be a growing market for medical devices over the next few years, because investments in medical technology are a necessary part of the process of bringing the national health care system up to European standards.

How is a medical device defined in Poland?

Medical devices legal regulations are found in "The Medical Devices Act of 20th April 2004", which contains definitions and laws concerning:

- marketing and implementation,
- clinical assessment,
- conditions of use,
- surveillance over manufacturing, marketing and implementation,
- procedure of reporting medical incidents,
- registering medical devices,
- authorities concerned with controlling medical devices,
- classification of medical devices,
- testing conformity of manufacturer or vendor registered medical devices,
- basic requirements for medical devices.

The above mentioned Act was prepared shortly before Poland's accession to the European Union and adapted Polish regulations to the relevant EU directives.

The Act describes medical devices as all tools, materials, apparatus, equipment and other devices which solely or jointly with other equipment or software have been designed by its producers to be used on (or in connection to) human beings during the following processes:

- diagnosing, prevention, monitoring, treating or easing the symptoms of illnesses,
- diagnosing, monitoring, treating or easing the symptoms of injuries and disabilities,
- conducting research, remodeling of human anatomy or physiological processes,
- contraception, where this is not achieved by using pharmaceutical, immunological or metabolic means (unless they are used as supplements).

The Act mentions three main groups of medical devices:

- active medical products for implantation – are defined as medical devices which depend on an external source of electricity or energy (not generated by the human body or by force of gravity) and which are permanently implanted into the body during surgery or via medical treatment,
- medical products which are used for in-vitro diagnosis including vacuum containers for samples and lab equipment for in-vitro research,
- multi-purpose medical devices – all other medical devices.

What is required to sell a medical device in Poland?

Polish law describes two different ways of bringing a medical device to market:

- "placing" – means the first time a medical device is made available (whether for free or sold) for use or distribution, regardless of whether it is new or fully refurbished. This does not apply to medical devices intended for clinical investigations or in-vitro diagnostic medical devices for performance evaluation.
- "putting into service" – means the stage at which a medical device is available to the final user (patient or health care professional) as being ready for use.

The law specifies a limited number of bodies that are allowed to register and sell medical devices. It is more important for manufacturers/distributors/sellers to have contracts or agreements confirming their status than to present health authorities with certificates confirming capability and being able to demonstrate experience in trading medical devices. The right documentation (as far as local law is concerned) is far more important than relevant experience.

Bodies mentioned in the Act are:

- medical device manufacturers,
- authorized representatives of medical device manufacturers,
- medical device importers,
- medical device distributors,
- specialized agencies and companies responsible for bringing medical devices to market.

Only medical devices which are compliant with Polish law i.e. both The Medical Devices Act and any other regulations in force that are relevant to a specific device are permitted to be sold. The three major requirements for medical devices are:

- compliance with the so-called 'basic requirements' mentioned in an ordinance issued by the Minister of Health, especially regarding designing, manufacturing, packaging and labeling of such products,

- a 'declaration of conformity',
- a 'CE' label (in cases of specific medical devices short transitional periods may apply).

There are rare exemptions to the above rules, which apply in very specific cases to single device units. It is also very important that the CE marking used for medical devices must conform with the rules described in the ordinance published by the Minister of Health.

Prior to launching, medical devices should be tested by a notification body in order to evaluate their conformity with legal requirements. The notification body must be in possession of an ID number issued by the European Commission and be listed in the Official Journal of the European Communities. A list of the Polish notification bodies is provided at the end of this White Paper. Provided local regulations are strictly followed, non Polish notification bodies are also acceptable.

All medical devices should be accompanied by a Polish language user's manual and description (including all markings, labels, etc.). However, an exemption exists for some medical devices designed to be used by professionals who consent to non-Polish language instructions. Even for products where the risks associated with improper use are much lower, it is highly unusual for professional companies to offer goods without good quality local language documentation. In addition to controlling the risk of legal action in the event of a "health incident", local translation helps ensure that the device is properly used and maintained.

In Poland medical devices are classified into six groups (four groups of multipurpose medical devices and two groups of specific use medical devices) depending on the potential hazards to human health through their usage. The list of groups and their description can be found in relevant regulations issued by the Minister of Health.

Where can medical devices be sold?

In Poland medical devices can be sold only in predefined types of retail and wholesale businesses. The Pharmaceutical Code (Act of 6 September 2001) lists the following types of outlets:

- pharmaceutical wholesalers,
- veterinarian pharmaceutical wholesalers,
- pharmaceutical retailers(pharmacies),
- small pharmacies,
- non-pharmacy retailer - some other retailers are allowed to sell pharmaceuticals, e.g. specialized retailers dealing in supplying hospitals and clinics only.

How to register medical devices?

Medical devices must be listed in the 'Register of medical devices and bodies responsible for their launch and usage" prior to marketing the device or its use by patients. This register is run by the Office for Registration of Medicinal Products, Medical Devices and Biocides. The first step to get the medical device registered is an application supplied by the manufacturer directly or a company authorized to do business with the manufacturer (e.g. an authorized representative or distributor) and registered in Poland. A special form should be used for this filing. A fee is payable (equivalent of €80 at the time of writing). Registry staff may require additional documents certifying and confirming statements made in the application. The application form and any attached documents should be prepared in Polish (despite the fact that the application form is bilingual), or translated by an approved Polish legal translator.

Given the speed of local bureaucracy it is recommended to double-check the application before submission to avoid being rejected, or suffering lengthy delays after two-month processing period.

The same Office is also responsible for registering 'medical incidents' which are described as defects in a medical device's functioning, a change of specification, improper marking or user's manual descriptions which might cause hazards to the patient. In each case the manufacturer or their representative is responsible for carrying out an investigation. Finding your medical device in the 'medical incidents' register may result in the product/company being delisted from the 'Register of medical devices and bodies responsible for their launch and usage', and as a consequence effectively barred from doing business in Poland.

Do you have to register your medical device if it already has CE approval?

As the list of medical devices registered in Poland shows at the end of this paper, companies like Bayer Healthcare, Olympus Diagnostica and Abbott Japan continue to register their devices (the table shows some of the devices registered in August 2004). It is possible to find government officials who claim that if you have CE marking you do not have to have the local approval. One such official was interviewed for this white paper. The actual practice, confirmed by the regulatory affairs specialist of a major international healthcare group, indicated that most hospitals and doctors will not consider buying products without a Polish PL/DR number. Thus even if in theory it may be possible to launch a product in Poland without local approval, commercial success very often requires it even if government officials may not. Application forms to take advantage of reciprocal CE recognition can be downloaded from the web site **www.bip.urpl.gov.pl**.

Quality control procedures

According to current Polish regulations medical devices which comply with legal requirements should be tested to make sure that using them will cause no harmful side effects. Clinical evaluations are carried out by the manufacturer of a medical device or by an authorized representative. The evaluation process should be based on three sources:

- combined data from available medical literature describing the application area in which the device will be used,
- a written study containing a critical analysis of the above mentioned data,
- results of clinical research conducted according to current legal requirements.

Both multipurpose and active medical devices for implantation require clinical research. Data obtained from secondary sources (e.g. medical literature) is not sufficient to perform the clinical evaluation. Such clinical research should be performed in order to:

- check whether the medical device's specification described by the manufacturer comply with basic requirements of Polish law,
- identify any possible harmful side effects which may occur during normal usage of the medical device.

Before starting clinical research works the entity responsible for carrying it out must obtain specific permits issued by a bioethical commission and the Office for Registration of Medicinal Products, Medical Devices and Biocides. Permits are payable within a range of €220 to €1,100.

Summary

This White Paper shows that, as in other countries, the regulatory issues concerning the sale of medical devices in Poland is complex and has to be taken seriously. For companies with competitive products that meet a medical need, this is a challenge they are familiar with and capable of grasping. Fortunately the market in Poland is large enough (together with its potential for sustained growth) to be make these challenges worth undertaking.

Sources:

1. Central Statistical Office
2. Ministry of Health of the Republic of Poland
3. Office for Registration of Medicinal Products, Medical Devices and Biocides
4. Act of 5 December 1996 on the profession of a doctor
5. Act of 27 July 2001 on the Office for Registration of Medicinal Products
6. Medical Devices and Biocides
7. The Medical Devices Act of 20th April 2004

Useful addresses:

Ministry of Health (Ministerstwo Zdrowia)

ul. Miodowa 15, 00-952 Warszawa
tel.: +48 22 634 96 00
fax: +48 22 634 96 00
e-mail: kancelaria@mz.gov.pl
internet: www.mz.gov.pl

Office for Registration of Medicinal Products, Medical Devices and Biocides (Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych)

ul. Ząbkowska 41, 03-736 Warszawa
tel.: +48 22 492 11 00
fax: +48 22 492 11 09
internet: www.bip.urpl.gov.pl

Notification bodies: (according to the Ministry of Health)

Testing and Certification Institute BBJ-SEP
Association of Polish Electrical Engineers
ul. M. Pożaryskiego 28, 04-703 Warszawa
tel.: +48 22 812 69 38
fax: +48 22 815 65 80
e-mail: bbj@bbj-sep.com.pl
internet: www.bbj-sep.com.pl

Eltest

ul. Ratuszowa 11, 03-450 Warszawa
tel.: +48 22 619 39 66
fax: +48 22 619 39 66
e-mail: sekretariat@eltest.com.pl
internet: www.eltest.com.pl

Institute of the Medical Technology and Devices (ITAM)

ul. Roosevelta 118, 41-800 Zabrze
tel.: +48 32 271 60 13
fax: +48 32 276 56 08
e-mail: itam@itam.zabrze.pl
internet: www.itam.zabrze.pl

Predom OBR

ul. Krakowiaków 53, 02-255 Warszawa
tel. +48 22 846 54 31
fax +48 22 846 19 05
e-mail: obr@predom.com.pl
internet: www.predom.com.pl

Polish Centre of Research and Certification (PCBC)

ul Kłobucka 23a, 02-699 Warszawa
tel. +48 22 857 99 16
fax. +48 22 647 11 09
e-mail: pcbc@pcbc.gov.pl
internet: www.pcbc.gov.pl

Bulletin of the office for registration of medicinal products, medical devices and biocides, including a list of medical devices entered in the register of medical devices and undertakings responsible for their introduction to trade and use (formerly: Register of medical manufacturers and devices – Art. 98.1 of the Medical Devices Act) for the period 1-31 August 2004

L.p.	Name (type, trade name)	Name and entry in the Register of Manufacturers	Entry in the Register of Medical Products (expiry date)
1	17-Hydroxycorticosteroids code: 11006 – 40 tests – thin-layer chromatography	BioSystems S.A., Spain PL/CA01 00079	PL/DR 007712
2	Abbott Determine Syphilis TP Serum/Plasma Assay	Abbott Japan Co., Ltd. Japan PL/CA01 01361	PL/DR 007789
3	Alkaline Phosphatase (ALP) OSR6103; Alkaline Phosphatase OSR6104, OSR6204 – clinical chemistry	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007807
4	ANAER 53638 – medium for anaerobes	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007724
5	Clinitek Status Analyser	Bayer Healthcare LLC, a subsidiary of Bayer Corporation USA PL/CA01 01450	PL/DR 007846
6	DCA 2000+ Analyser self-contained bar-coded test cartridge, specifications attached	Bayer Corporation: Diagnostics Division USA PL/CA01 02537	PL/DR 007791
7	Anatomic C System total cemented/cementless anatomical prosthesis for the hip joint with instruments, specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007708
8	Senographe 700 T/ 800 T digital mammography system	Ge Medical Systems Europe, societe en Commandite Simple France PL/CA01 01768	PL/DR 007830
9	Automix-Tips Blue 1:1 Packaging: 50 tips, 100 tips – mixing tips	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007740
10	Automix-Tips Blue 10:1 packaging: 45 tips – mixing tips	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007741
11	Auto Ref/Keratometer ARK-730A	NIDEK Co. Ltd. Japan PL/CA01 01646	PL/DR 007848
12	Avalon CTS (Cordless Transducer System) wireless foetal and maternal surveillance monitor including: M2720A base station, transducers (Toco M2725A, US M2726A, ECG M2727A), and ACCESSORIES, specifications attached	Philips Medizin Systeme Boeblingen GmbH Germany PL/CA01 00696	PL/DR 007755
13	AxSYM Acetaminophen Reagent Pack, AxSYM Acetaminophen Master Calibrators, X SYSTEMS Acetaminophen Calibrators, X SYSTEMS Acetaminophen Controls	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007853
14	AxSYM Core-M Reagent Pack, AxSYM Core-M Controls – Hepatitis B Core Antigen (Anti-HBc IgM)	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007851
15	AxSYM Opiates Reagent Pack, X SYSTEMS Opiates Calibrators – opiates	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007855
16	AxSYM Phenobarbital Reagent Pack, AxSYM Phenobarbital Standard Calibrators, AxSYM Phenobarbital Controls – Phenobarbital	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007856
17	AxSYM REA Ethanol reagent Pack, AxSYM REA Ethanol Master Calibrators, TDx/TDxFLx REA Ethanol Reagent Pack, X SYSTEMS REA Ethanol Calibrators, X SYSTEMS REA Ethanol Serum Controls, X SYSTEMS REA Ethanol Whole Blood Controls	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007854
18	AxSYM Tricyclic Antidepressants Reagent Pack, AxSYM Tricyclic Antidepressants Master Calibrators, X SYSTEM Tricyclic Antidepressants Calibrators, X SYSTEM Tricyclic Antidepressants Controls – Tricyclic antidepressants	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007793
19	Basic Fragment Set – set of screws and plates for osteosynthesis, specifications attached	Stryker Trauma AG Switzerland PL/CA01 00197	PL/DR 007742
20	BC Thrombin Reagent Ref No. OWNA11 – biochemical test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 0007778
21	BC Vial Kit Ref. No. OVKE 292 – materials for immunological tests	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007786
22	Berichrom Factor XIII Ref. No. OWSU 11 – blood coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007763
23	BUFFERED DEXTROSE 53364 – medium for streptococcus	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007718
24	Calcium (Arsenazo) OSR6176, OSR6276 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007801
25	CCI System total prosthesis for the knee joint with instruments, specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007707
26	CEA ELISA - EIA - 1871 – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007761
27	Cellognost RF Combipack 50 Ref. No. OSHA 115 – immunological tests	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007781

28 Cellognost RF Ref. No. OSHB 095 – immunological tests	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007783
29 Criticath catheter, specifications attached	Becton Dickinson Critical Care Systems Pte Ltd Singapore PL/CA01 00423	PL/DR 007871
30 HDC V-CATH intravenous catheter with introducer, specifications attached	HDC Corporation USA PL/CA01 02135	PL/DR 007814
31 CK-MB OSR6153 – clinical chemistry (reagents)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007803
32 Coagulation Factor XI Deficient Plasma Ref. No. OSDF 13 – coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007782
33 Coagulation Factor XII Deficient Plasma Ref. No. OSDG 13 – coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007775
34 COLUMBIA 64678, COLUMBIA 64674 – medium for demanding bacteria	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007725
35 CR-Stem System total cemented/cementless prosthesis for the hip joint with instruments specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007710
36 Cryotome SME 77200001, 77200002, 77200004, 7720005, including standard accessories usually included with the product and Kriostat accessories, specifications attached	Thermo Electron Corporation UK PL/CA01 02540	PL/DR 007844
37 dade Dimertest Latex Assay Ref. No. B4233-60 – coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007767
38 Densytometer DT-93, DT-93XY	EMCO Sp. Z o.o. Poland PL/CA01 00952	PL/DR 007823
39 Dental abrasives and polishers, specifications attached	Jota AG Switzerland PL/CA01 02826	PL/DR 007821
40 Direct Bilirubin OSR6111, 6211 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007806
41 Dry Coat, packaging: 30ml bottle – lacquer	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007736
42 ENDOMETHASONE liquid, ENDOMETHASONE packaging: 10ml bottle – eugenol with zinc oxide	Septodont France PL/CA01 00516	PL/DR 007733
43 ENDOMETHASONE N, packaging: bottle with 14g/42g powder; set: 3 bottles with 14g powder; set: 1bottle with 14g powder +1 bottle with 10ml liquid (Eugenol) – root canal sealer	Septodont France PL/CA01 00516	PL/DR 007732
44 ENDOPEROX POWDER – bleaching of pulpless teeth	Septodont France PL/CA01 00516	PL/DR 007734
45 Epiphany Soft Resin Endodontic Obturation System – soft resin obturation material for root canal filling, specifications attached	Pentron Clinical Technologies USA PL/CA01 00265	PL/DR 007826
46 FUNGITEST (60790) – broth for susceptibility testing of yeasts to anti-fungal antibiotics	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007817
47 GEM DR – Implantable automatic cardioverter defibrillator; Model: 7271	Medtronic Inc. USA PL/CA01 00022	PL/DR 007835
48 Glass Capillary Tubes 5µl Ref. No. OTCL 212 – auxiliary materials for coagulation tests (test tubes)	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007870
49 Gold Core 73LS (cubes formed into flat bars) – yellow gold base alloy for high expansion low fusing ceramics	Pentron Clinical Technologies USA PL/CA01 00265	PL/DR 007827
50 HDL-Cholesterol Calibrator ODC0011; LDL-HDL Cholesterol Control Serum ODC0005; LDL-Cholesterol Calibrator ODC0012 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007808
51 HYPERTRONIC BROTH 53384 – medium for enterococcus	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007719
52 ic-Straight Stem total cemented prosthesis for the hip joint with instruments, specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007709
53 IgE ELISA - EIA - 1788 – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007759
54 Acupuncture needles, specifications attached	Wujiang City Cloud & Dragon Medical Device Co. Ltd. China PL/CA01 03052	PL/DR 008057
55 Imx Insulin reagent Pack, Imx Insulin Calibrators, Imx Insulin Controls – insulin	Abbott Japan Co., Ltd. Japan PL/CA01 01361	PL/DR 007790
56 Medel Family Basic Pneumatic inhalator, Silver	Medel S.p.A. Italy PL/CA01 01093	PL/DR 007831
57 Sterile single-use injection needles, size 14G-30G	ERG Kłobuck Spółka Akcyjna Poland PL/CA01 01684	PL/DR 007815
58 Central EU-C60 USG unit with EUS EXTERA video endoscopes and additional equipment, specifications attached	Olympus Corporation Co., Ltd. Japan PL/CA01 02349	PL/DR 007832
59 Biochemical calibrator Catalogue No. 18011	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007788
60 Capillary for blood tests with accessories, specifications attached	S.C. sanguis Counting GmbH Germany PL/CA01 02343	PL/DR 007865
61 KING A 55274, KING B 55278 – bacteriological medium in test tubes for differentiation of Pseudomonas	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007717

62 KLIGER-HAJNA 64844, KLIGER-HAJNA 55378 - bacteriological medium for differentiation of Enterobacteriaceae	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007731
63 ONPG Discs(ONPG) Ref No. 55601 (1 bottle); Cefinaza (CEF-F) Ref No. 555622 (50 discs)	Biomerieux S.A. France PL/CA01 00289	PL/DR 007798
64 Discs from other group, specifications attached	Biomerieux S.A. France PL/CA01 00289	PL/DR 007799
65 Discs from Macrolide group, specifications attached	Biomerieux S.A. France PL/CA01 00289	PL/DR 007861
66 Discs from Penicillin group, specifications attached	Biomerieux S.A. France PL/CA01 00289	PL/DR 007862
67 Discs from Tetracycline group, specifications attached	Biomerieux S.A. France PL/CA01 00289	PL/DR 007800
68 LA1 Screening Reagent Ref. No. OQGP 152 – coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007770
69 LA2 Confirmation Reagent - Ref. No. OQGR 11 – coagulation test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007772
70 Lactate Dehydrogenase OSR6126 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007805
71 SL-8Z Elite Slit Lamp	TOPCON Corporation Japan PL/CA01 01126	PL/DR 007838
72 LARGAL ULTRA chelating agent for the chemical reaming of root canals, packaging: 13ml	Septodont France PL/CA01 00516	PL/DR 007735
73 Nd/YAG MARTIN MY 40 1.3 laser with accessories	Gebrueder Martin GmbH & Co. KG Germany PL/CA01 00585	PL/DR 007752
74 LC Partigen C1q Ref. OURT 035 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007785
75 LOAD-SHIFT System total prosthesis for the hip joint with instruments, specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007711
76 Sterile connections for drainage tubes and catheters; Cat. No. AK30, AK31, AK32, AK33, AK34, AK53, PB01, PB02, PB12	Porges S.A. France PL/CA01 00215	PL/DR 007748
77 MAC CONKEY+CRISTAL VIOLET 69084, 63617 – medium for enterobacteriaceae	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007727
78 MEAT LIVER DEXTROSE 53614, MEAT LIVER 0.6% 54716, MEAT LIVER 0.6% 64564 – bacteriological medium for aerobic and anaerobic bacteria	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007730
79 MICRONIUM EXCLUSIV – chrome-cobalt-molybdenum alloy for skeletal prosthesis	Schuetz-Dental GmbH Germany PL/CA01 01161	PL/DR 007840
80 OP-2 operating microscope	Ohira Co., Ltd. Japan PL/CA01 02573	PL/DR 007836
81 Control sample of urine, codes: 18036, 18037	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007715
82 Model Impresario: Solo, Ensemble, Symphony – ECG analysis program	Del Mar Reynolds Medical Ltd. UK PL/CA01 02528	PL/DR 007833
83 Monitors measuring midbrain pressure FV500, FV501, FV502, FV503, FV504, FV505 with accessories, specifications attached	Spiegelberg Germany PL/CA01 02275	PL/DR 007751
84 Monoclonal Anti-RH1 (D)/RHW1 – monoclonal human antibodies to mark RH1 antigen	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007841
85 Monoclonal RH/K phenotypes – gel with monoclonal human antibodies to mark the following antigens: RH2, RH3, RH4, RH5, KEL1	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007842
86 MONOLISA Anti-HCV PLUS Version 2: 1 plate 96 tests Cat. No. 72 317; 5 plates 480 tests Cat. No. 72 378 – immunoenzyme test to detect antibodies for hepatitis C (HCV) in human serum or plasma	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007816
87 MULTI-LINK VISION – Artery Stent System. Type: RX, OTW, specifications attached	Guidant Corporation USA PL/CA01 02809	PL/DR 007824
88 MUTARS, cemented/cementless modular revision prosthesis for proximal and distal part of the femoral bone; proximal part of the tibial bone; proximal and distal part of the humeral bone, with instruments, specifications attached	Implantcast GmbH Germany PL/CA01 03051	PL/DR 007706
89 MYCOPLASMA DUO suspension medium (62739) MYCOPLASMA DUO (62740) – test to identify and mark urogenital mycoplasma using titre	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007818
90 Mycoplasma pneumoniae Antigen Ref. No. OTHI 05 (5) – virology test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007771
91 Mycoplasma pneumoniae Control Antigen Ref. No. OTHL 05 (5) – virology test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007765
92 Mycoplasma pneumoniae Control Serum Ref. No. OTHK 03 (5) – virology test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007764
93 Myoglobin OSR6168 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007802
94 N AS IgG2 Ref. No. OQXK 092 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007766
95 N Latex IgA Ref. No. OQAI 115 – immunological tests	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007768
96 N Latex IgM Ref. No. OQAC115 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007779

97	NEISSERIA-GC AGAR BASE 69354, NEISSERIA-GC medium base 69354 – medium for isolation of Neisseria	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007729
98	NICOR nickel and chrome alloy for crowns and ceramic bridges	Schuetz-Dental GmbH Germany PL/CA01 01161	PL/DR 007839
99	NOR-Partigen Antithrombin III Ref. No. OSLC035 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007774
100	NUTRITIVE BROTH 1.3% + NaCl 53446 – nutritive medium	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007720
101	OPTIMA PT volumetric infusion pump	Fresenius Vial S.A.S. France PL/CA01 02567	PL/DR 007849
102	SANITY breast pump; SANITY Lux breast pump	Albert Poland Sp. z o.o. Poland PL/CA01 00070	PL/DR 007754
103	Reagents for clinical chemistry for series: 238, 480, 600 – self-contained system, specifications attached	Bayer Healthcare LLC, a subsidiary of Bayer Corporation USA PL/CA01 01450	PL/DR 007847
104	List A reagents for the self-contained Access immunological analyzer system, specifications attached	Beckman Coulter Inc. USA PL/CA01 00674	PL/DR 007796
105	List B reagents for the self-contained Access immunological analyzer system, specifications attached	Beckman Coulter Inc. USA PL/CA01 00674	PL/DR 007795
106	ONE-SHOT STERILE SINGLE-USE DENTAL INJECTION NEEDLES, Versions: 25-GAUGE SHORT (RED); 25-GAUGE LONG (RED); 27-GAUGE SHORT (YELLOW); 27-GAUGE LONG (YELLOW); 30-GAUGE SHORT (BLUE); 30-GAUGE X-SHORT (BLUE)	SULTAN Chemists, Inc. USA PL/CA01 02568	PL/DR 007745
107	Endoscopy optics (hysteroscopy, laparoscopy, arthroscopy, and others,) specifications attached	WISAP GmbH Germany PL/CA01 02820	PL/DR 007744
108	PenCeram 75YB (cubes formed into flat bars) – gold base alloy for ceramic bridges	Pentron Clinical Technologies USA PL/CA01 00265	PL/DR 007828
109	PermaCem - Automix Dual packaging: 1 cartridge (52g); 35 Automix-Tips – compounds for fillings, ceramic crowns, inlays, etc.	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007739
110	Loops for polypectomy: P1 – symmetrical/asymmetrical; size: 160cm, Cat. No. 0510XXXXX); P2 – symmetrical/asymmetrical; size: 230cm., Cat. No. 0520XXXXX (XXXXX – any digits)	MTW - Endoskopie Germany PL/CA01 01482	PL/DR 007825
111	PNEUMOCOCCUS 53574 – medium for pneumococcus	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007722
112	Anticardiolipine antibodies (ACA) Code: 44780	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007713
113	Anti-Islet Cell Antibodies (AICA) Code.: 44609, 44572	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007714
114	PSEUDOMONAS AERUGINOSA 55857, PSEUDOMONAS AERUGINOSA 63914, PSEUDOMONAS AERUGINOSA 64804 – medium for Pseudomonas	Bio-Rad Laboratories, France PL/CA01 00494	PL/DR 007726
115	Rapidchem 754 with accessories – self-contained analyzer system with accessories	Bayer Healthcare LLC, a subsidiary of Bayer Corporation USA PL/CA01 01450	PL/DR 007504
116	Kinyoun solution (BKK-F)Ref. No. 55521 (450ml), Gabett solution (BKG-F) Ref. No. 55531 (450ml) – colouring solution	Biomerieux S.A. France PL/CA01 00289	PL/DR 007857
117	Rib spreaders	Max Hauser Suddeutsche Chirurgie-Mechanik GmbH Germany PL/CA01 03017	PL/DR 007665
118	Rx G-Universal (cubes formed into flat bars) – gold base alloy for ceramic bridges	Pentron Clinical Technologies USA PL/CA01 00265	PL/DR 007829
119	Paper filters	Precise Dental International Mexico PL/CA01 01163	PL/DR 007747
120	SEPTOJECT XL cartons with 100 same-size needles. Available needle sizes: 30G 8mm, 30G 12mm, 30G 16mm, 30G 221mm, 30G 23mm, 30G 25mm and 27G 8mm, 27G 12mm, 27G 16mm, 27G 21mm, 27G 25mm, 27G 32mm, 27G 35mm	Septodont France PL/CA01 00516	PL/DR 007746
121	ELISA Serotonin Cat. No. RE 59121, 12x8 tests	IBL Immuno-Biological Laboratories GmbH Germany PL/CA01 02346	PL/DR 007868
122	Shandon Citadel 1000, Shandon Citadel 2000: 69800001-6980008 (inclusive) – tissue processor	Thermo Electron Corporation UK PL/CA01 02540	PL/DR 007843
123	Shandon Pathcentre 75200011, 75200012, 75200013, 75200014, 75200111, 75200112, 75200113, 75200114, A75200022, A75200122 – tissue processor	Thermo Electron Corporation UK PL/CA01 02540	PL/DR 007845
124	Single-use brushes, packaging: 25 pieces	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007737
125	Medi-Pac 44 Rescue Seat	Ferno-Washington, Inc. USA PL/CA01 02259	PL/DR 007756
126	Slidex pneumo-Kit 2 Ref. No. 58821 (50 tests) – latex test	Biomerieux S.A. France PL/CA01 00289	PL/DR 007860
127	Slidex Rota-Kit 2, Ref. No. 58842 (30 tests) – latex test	Biomerieux S.A. France PL/CA01 00289	PL/DR 007859

128 Small Fragment Set – set of screws and plates for osteosynthesis with instruments, specifications attached	Stryker Trauma AG Switzerland PL/CA01 00197	PL/DR 007743
129 Smartmix-Tips Combi packaging: 50 items with mixing tips	DMG Chemisch-Pharmauzeutische Fabrik GmbH Germany PL/CA01 00147	PL/DR 007738
130 Sperm Antibody ELISA -EIA-1826 (SPAK) – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007760
131 STAPHYLOCOAGULASE BROTH 53544 – medium for detection of Staphylococcal coagulase	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007721
132 Sterile canal instruments for single use and re-usable, specifications attached	VDW GmbH Germany PL/CA01 02315	PL/DR 007820
133 Sterile Petri dishes, specifications attached	ROLL S.a.s di Finotto M.&C. Produzione articoli per laboratori analisi Italy PL/CA01 01095	PL/DR 007866
134 Stomach tube; sizes: F8- F24, length: 1250mm ± 30mm	Jiangsu Kaishou Medical Apparatus CO.,LTD China PL/CA01 00537	PL/DR 007813
135 Control serum for CK-MB; Code.: 18024	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007716
136 Access 81600 Immunological Analyzer self-contained system with reagents, specifications attached	Beckman Coulter Inc. USA PL/CA01 00674	PL/DR 007794
137 Syva Rapidtest d.a.u. 10 Ref. No. 6A289UL – test for mark of narcotics and pharmaceuticals	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007810
138 Syva Rapidtest d.a.u. AMP Ref. No. 6A059UL – test to mark levels of narcotics and pharmaceuticals	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007812
139 Syva RapidTest d.a.u. BAR Ref. No. 6A079UL – test to mark narcotics and pharmaceuticals	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007863
140 Syva Rapidtest d.a.u. mAMP Ref. No. 6A039UL – test to mark narcotics and pharmaceuticals	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007811
141 Syva Rapidtest d.a.u. TCA Ref. No. 6A119UL – test to mark level of narcotics	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007809
142 Syva RapiTest d.a.u. 9 Ref. No. 6A279UL – test to mark level of narcotics and pharmaceuticals	Dade Behring Inc., Syva USA PL/CA01 01007	PL/DR 007864
143 T.G.Y. 53624 – medium for anaerobic bacteria	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007723
144 T3 ELISA - EIA-1780 – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007758
145 T3 FREE ELISA – EIA - 2385 – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007762
146 TDx/TDxFLx Benzodiazepines Serum Reagent Pack, X SYSTEMS Benzodiazepines Serum Calibrators, X SYSTEM Benzodiazepines Serum Controls – benzodiazepines	Abbott Laboratories Diagnostic Division USA PL/CA01 00404	PL/DR 007852
147 TS-p (TS-92) Thermostat	EMCO Sp. Z o.o. Poland PL/CA01 00952	PL/DR 007822
148 Test to confirm infection with HIV1 and HIV2: New Lav Blot I; New Lav Blot II	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007753
149 Toxo-ISAGA Ref. No. 75361 (384 catch basins); Toxotrol Ref. No. 75411 (8x0,5ml), Toxo-Spot IF Ref No. 75471 (100 discs), Toxo Screen DA Ref. No. 75481 (4x96 catch basins) – serological tests	Biomerieux S.A. France PL/CA01 00289	PL/DR 007858
150 TPHA 100 Ref. No. 72492 (96 tests) – serological tests	Biomerieux S.A. France PL/CA01 00289	PL/DR 007797
151 TPHA Cat. No. 36005 – hemaglutanin test	BioSystems S.A. Spain PL/CA01 00079	PL/DR 007787
152 Turbiquant acid $á_1$-Glucoprotein Ref. No. OWLS 355 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007773
153 Turbiquant Albumni Ref. No. OUVI 355 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007780
154 Turbiquant Apolipoprotein A-I Ref. No. OUUK355 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007776
155 Turbiquant C4 Ref. No. OUSR355 – reagent for quantitative analysis of human serum for complement complex determination	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007784
156 Turbiquant Transferrin Ref. No. OUSM 35 – immunological test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007777
157 Urea STAT OSR6141 – clinical chemistry (reagent)	Olympus Diagnostica GmbH (Irish Branch) Ireland PL/CA01 00540	PL/DR 007804
158 VMA ELISA - EIA - 1620 – immunoenzyme test	DRG Instruments GmbH Germany PL/CA01 00351	PL/DR 007757
159 Wenzygnost Anti-Masern Virus/IgG Ref. No. OWLN15 (5) – virology test	Dade Behring Marburg GmbH Germany PL/CA01 00368	PL/DR 007769
160 MPW-15 laboratory mini centrifuge	MPW - Med.instrumenmts Spółdzielnia Pracy Poland PL/CA01 01782	PL/DR 007837
161 ELISA Free Tesosterone Catalogue No. RE 52171 12x8 tests	IBL Immuno-Biological Laboratories GmbH Germany PL/CA01 02346	PL/DR 007792
162 swabbing sets – containers for biological material No. 80.625.xxx, 80.627.xxx, 80.628.xxx.	Sarstedt Akiengesellschaft & CO., Kommanditgesellschaft Germany PL/CA01 00123	PL/DR 007749
163 X.L.D. 41751 X.L.D. 69124 – medium for Enterobacteriaceae	Bio-Rad Laboratories France PL/CA01 00494	PL/DR 007728
164 ZAN600 ErgoTest – breath analyser	ZAN Messgerate GmbH Kardiopulmonale Funktionsdiagnostik Germany PL/CA01 02808	PL/DR 007834

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