MEDICAL DEVICE DESCRIPTION	
Ref.	**BMS IMPLANT II**
Product Image	
Destination of use	The BMS IMPLANT II is a medical device which can be used in general surgery of hard tissues in the fields: 1. dental, for bone and implant surgery, endodontics; 2. maxillo-facial surgery, ENT surgery, orthopedics, neurosurgery and general surgery of hard tissues. The BMS IMPLANT II device can be used in all clinical field, where a controlled actioning is required, through the torque control of tools for drilling, as the insertion of prothesic implants in the human field and in surgycal operations.
Product description	BMS IMPLANT II medical device is a surgical equipment characterized by an accurate torque control of the motor in the handpiece.
MANUFACTURER	
Esacrom srl – Via Zambrini, 6/A – Imola (BO) Italy	

Esacrom s.r.l. Via Zambrini, 6/A 40026 Imola (Bo) P.IVA 02007591205 R.E.A Bo n° 64274 Tel. + 39 0542 643527 Fax +39 0542 482007

TECHNICAL DATA	
Voltage Supply	230Vac 50/60Hz - 115 Vac 50/60Hz
Nominal power	170 [VA]
Console weight	4,5 [Kg]
Handpiece cable lenght	2000 [mm]
Hydraulic circuit flow	From 5 to 50 [ml/min]
Fuses	EXTERNAL FUSES F1-F2=T 1,6A (230Vac) F1-F2=T 3,15A (115Vac) INTERNAL FUSES F1=1xT 1A, F2=1xT 0,5A, F3=1xT 5A
Micromotor data	The console allows to set: motor speed (expressed in ramp per minute), torque value (expressed in Newton per centimeter), reduction ratio or contrangle multiplication, number of degrees and of turns clockwise, number of degrees or of turns anticlockwise and the pump's flow. **FUNCTIONS:** Drill, Ream, Implantologia, Protesi, Endo 10 programs for each function are available. **MOTOR:** Brushless with hall sensors Speedness: 200-40.000 Rpm **HANDPIECE WEIGHT**: 182 [g] – *with connection cable*
Packaging	**Transport case in box – dimensions: 24,5x44x61,5 [cm]**

CLASSIFICATION	
Dir.93/42/CEE-Dir. 2007/47/CE	**Class IIb**
EN 60601-1	**Class I Type B**
RDM (Medical Devices Repertory Registration n.)	**9355/R**
CND (Medical Device National Classification Code)	**Z129099** *(VARIOUS EQUIPMENT FOR FUNCTIONAL EXPLORATIONS AND THERAPEUTIC INTERVENTIONS NOT OTHERWISE CLASSIFIED)*

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GMDN (Global Medical Device Nomenclature Code)	**36273** **Ultrasonic surgical system generator** *An electrically-powered component of an ultrasonic surgical system intended to generate a high frequency electrical current that is converted, typically within a handpiece, into an ultrasonic oscillation to fragment hard and/or soft tissue cells upon contact with a vibrating tip. it is used in a variety of surgical disciplines (e.g., arthroscopy, gynaecology, neurosurgery, dental/craniomaxillofacial reconstructive surgery); it is not dedicated to dental applications. It provides the controls and monitoring functions for the system during the procedure, and typically regulates energy to the system via a foot-switch; integrated suction/aspiration function may be included*
UMDNS (Universal Medical Device. Nomenclature System Code)	.....
CPV 2007 **Public procurement code**	**33100000-1** Medical equipments.

APPLICABLE STANDARD AND DIRECTIVES	
Directives:	**Medical Devices:** Dir. 93/42/EEC as modified Dir. 2007/47/EEC **Machines:** Dir. 2006/42/EEC
Standards:	**Electrical safety**: EN 60601-1; EN60601-1-6; IEC 62304; IEC 62366 **Electromagnetic compatibility:** es. EN60601-1-2

HOMOLOGATIONS-APPROVALS
CE 0051 Certification – Notified Body IMQ – certificate CE n°874/MDD

PRESERVATION	
Sterility:	Not sterile DM
Sterilization method:	Not sterile DM
Expiry:	Not sterile DM

INSTALLATION	
Installation area:	Installation on a table/cart, far from heat sources
Environmental parameters	**Temperature**: from 5 to 40°C **Humidity**: less than 90%

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Electrical connection	By removable supply cable
UPS Power Supply	User's discretion according to the safety procedures in use at user facility.
Gas network connection	Not necessary
Water supply Connection	Not necessary
Connection data	Not necessary

MAINTENANCE

The device is maintenance free. The only **routine** maintenance in charge to the user are:
• Cleaning, disinfecting and sterilizing the handpiece and tips
• Cleaning and disinfection console
• Replace tubing and cooling solution
The manner in which these activities are to be made are shown in the **user manual**.

In order to maintain the standards of **electrical safety** guaranteed by Esacrom srl it is advisable to carry a functional control and verification of compliance with safety EN60601-1 for medical devices, to be performed with secure - tester, **AT LEAST ANNUALLY**.

Immediate maintenance by Esacrom srl or authorized personnel, must be performed if:

(1) the medical device has been subjected to external mechanical stresses, such as serious falls;

(2) the medical device has been subjected to extensive heating, for example, if left near a source of intense heat;

(3) it is doubtful that liquids can be penetrated inside;

(4) the casing or other parts of the medical device are damaged, broken or missing;

(5) the functionality of the medical device appears altered

Access the internal parts should be done by service personnel authorized by Esacrom srl. For repairs and additional information is necessary to contact Esacrom srl.

Technical assistance of the medical device BMS IMPLANT II is supplied primarily by Esacrom srl.

DISPOSAL

For the EU territory: According to European Directive Rohs 65-2011-UE and transposed into national legislation Disposal of AEE.

EU Extra: According to national rules on the disposal of electronic equipment for medical use.

STANDARD EQUIPMENT

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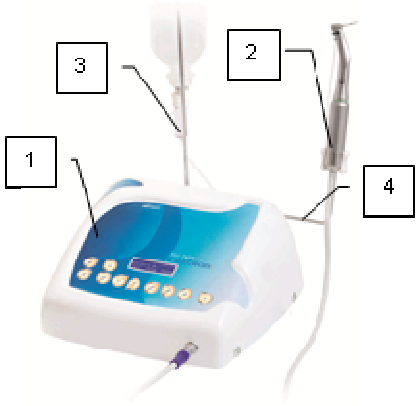
Description

In addition an irrigation tube, an electric cable, 2 fuses 1,6 A 250 V, tray, the warranty certificate, the conformity declaration and the user manual, default parameters, biological risk, Book Tips will be included to the package. The bag is also supplied. With each device Esacrom supply the **Production Report** filled with date and signature



Id.	Componente
1	Console complete of peristaltic pump
2	Micromotor handpiece with cable
3	Metal bar for cooling liquid
4	Micromotor handpiece holder
5	Pneumatic pedal

User Manual is supplied.

Accessories

Irrigation line	**Brand: OMNIA - SET IRR 32.F0271.00**

WARRANTY

Console: 2 Years ; Handpiece : 1 year

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