MEDICAL DEVICE DESCRIPTION	
Ref.	**SURGYSONIC MOTO**
Product Image	
Destination of use	The SURGYSONIC MOTO is a medical device which can be used in general surgery of hard tissues and soft tissues in the fields: 1. dental, for bone and implant surgery, endodontics and periodontal surgery; 2. maxillo-facial surgery, ENT surgery, orthopedics, neurosurgery and general surgery of hard tissues 3. in surgery of soft tissues: for wound management field for debridement, surgery of soft tissues, for interventions on bedsores, for the removal of necrotic tissue surface in the dermatological field (for the removal of necrotic tissue from the bottom of the ulcerative lesion, for the cleaning and cleansing of the same - debridement) The unit manages the ultrasonic handpiece which has also the following field of use: surgery field, where it is necessary to make cuts and/or incisions of bone (osteotomy) and/or hard tissues in general and / or soft tissues.
Product description	SURGYSONIC MOTO medical device is a surgycal equipment caracterised by a control issuing an ultrasonic vibration for hard and soft tissues' surgery. The unit manages a piezoelectric handpiece operating through an ultrasonic vibration (can be also a Led Handpiece).
MANUFACTURER	
Esacrom srl – Via Zambrini, 6/A – Imola (BO) Italy	

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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	Da 5 a 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
Piezoelectric data	The console allows to set the ultrasound vibration frequency, the ultrasound power and the water flow (70 different power levels usable with 10 different level of vibration). **VIBRATION:** 20/200 [µm] **FREQUENCY:** 22/35 [KHz] **FUNCTIONS:** Surgery, Normal, Sweep *, Turbo, Endo Possibility of manual set of this default function in use (power parameter from 0 to 70 with step of 1 point, vibra parameter from 0 to 100 with step of 10 point, pump parameter from 0 to 100 with step of 1 point). All modification can be memorized selecting MEM key. For Surgery, Normal and Endo function the maximum power to be set is 50. 10 programs for each function are available. **POWER:** 50W Surgery 50W Normal 70W Sweep* **(* see note)** 70W Turbo 50W Endo **HANDPIECE WEIGHT**: 182 [g] – *with connection cable* ***Note: * for Sweep function*** ***Sweep=Torsional mode***: This modality includes the **Sweep** type wave. In this modality the vibration frequency **is modified dynamically** between the value set in the VIBRA function and a value lower of 40 points. For instance, if you set the VIBRA parameter at 60, the vibration generated on the tip will go from 60 to 20. The frequency moves automatically, for exemple: to 70 to then return to 80, move to 90 to then return again to 80 according to hard tissue density on which the tip is working. It is an advantage and a benefit for treatment on the surgical area.
Packaging	**Transport case in box – dimensions: 24,5x44x61,5 [cm]**

CLASSIFICATION	
Dir.93/42/CEE-Dir. 2007/47/CE	**Class IIb**

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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)*
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

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

MANTAINANCE

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 SURGYSONIC MOTO 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.

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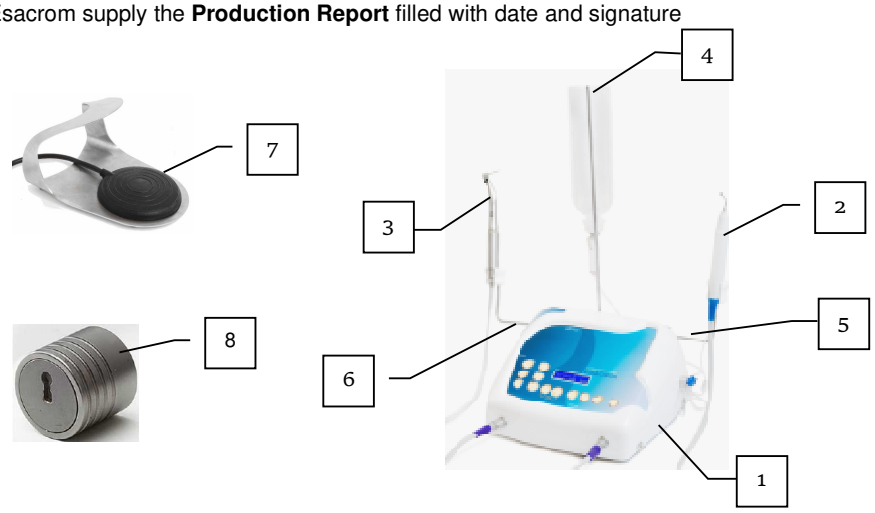
STANDARD EQUIPMENT

Description

In addition an irrigation tube, an electric cable, 2 fuses 1,6 A 250 V, tray, surgy port, 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	Ultrasonic Handpiece (piezo) with cable
3	Micromotor handpiece with cable
4	Metal bar for cooling liquid
5	Ultrasonic handpiece holder
6	Micromotor handpiece holder
7	Pneumatic pedal
8	Torque wrench for the tips of ultrasonic handpiece

User Manual is supplied.

Accessories

Irrigation line	**Brand: OMNIA - SET IRR 32.F0271.00**
Tips	SURGYSONIC MOTO devices are supplied with a set of tips. The complete list of available tips is published in the "Brochure" attached to the User Manual Guide. **The only tips to be used with Esacrom device are ONLY ESACROM tips.**

WARRANTY

Console 2 Years ; Handpieces : 1 year

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