

**MEDICAL DEVICE DESCRIPTION**

Ref.	SURGYSONIC II
<b>Product Image</b>	
<b>Destination of use</b>	<p>THE <b>SURGYSONIC II</b> is a medical device which can be used in general surgery of hard tissues in the fields</p> <ol style="list-style-type: none"> <li>1. Dental, for bone and implant surgery, endodontics and periodontal surgery;</li> <li>2. maxillo-facial surgery, ENT surgery, orthopedics, neurosurgery and general surgery of hard tissues</li> </ol> <p>In soft tissues surgery:</p> <p>for wound management in the dermatology field, for interventions of removal of necrotic tissue from the bottom of the ulcerative lesion, for the cleaning and cleansing of the same (debridement) and for soft tissues' surgery, wound management field for debridement, surgery of soft tissues, for interventions on bedsores, for the removal of necrotic tissue surface in the dermatological field.</p> <p>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.</p>

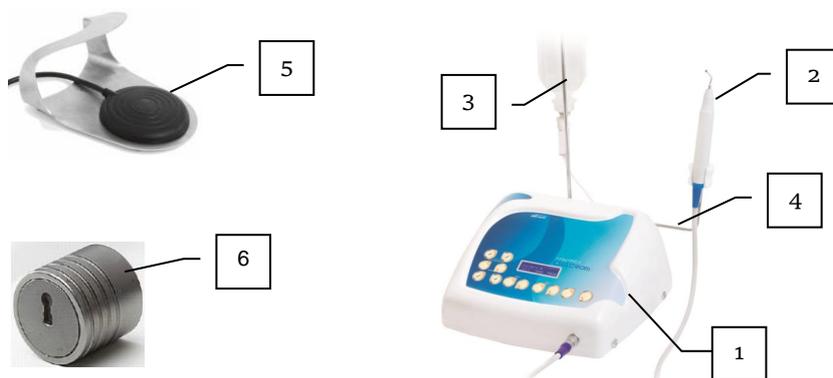
<b>Product description</b>	<p><b>SURGYSONIC II</b> medical device is a surgical equipment characterised by a control issuing an ultrasonic vibration for hard and soft tissues' surgery. The unit manages an ultrasonic handpiece, (can be also a Led Handpiece).</p>	
		
<b>MANUFACTURER</b>		
Esacrom srl – Via Zambrini, 6/A – Imola (BO) Italy		
<b>TECHNICAL DATA</b>		
<b>Voltage Supply</b>	230Vac 50/60Hz - 115 Vac 50/60Hz	
<b>Nominal power</b>	170 [VA]	
<b>Consolle weight</b>	4,5 [Kg]	
<b>Handpiece cable lenght</b>	2000 [mm]	
<b>Hydraulic circuit flow</b>	Da 5 a 50 [ml/min]	
<b>Fuses</b>	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	
<b>Piezoelectric data</b>	<p><b>VIBRATION:</b> 20/200 [µm]  <b>FREQUENCY:</b> 22/35 [KHz]  <b>FUNCTIONS:</b> Surgery, Normal, Endo  <b>POWER:</b> 48W Surgery                            50W Normal                            50W Endo  <b>HANDPIECE WEIGHT:</b> 182 [g] - <i>with connection cable</i></p>	
<b>Packing</b>	<b>Transport case in box – dimensions: 24,5x44x61,5 [cm]</b>	
<b>CLASSIFICATION</b>		
<b>Dir.93/42/CEE-Dir. 2007/47/CE</b>		<b>Class IIb</b>
<b>EN 60601-1</b>		<b>Class I Type B</b>
<b>RDM</b> ( Medical Devices Repertory Registration n.)		<b>291962/R</b>

<b>CND</b> (Medical Device National Classification Code)		<b>Z129099</b> (VARIOUS EQUIPMENT FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC MEASURES NOT OTHERWISE CLASSIFIED)
<b>GMDN</b> (Global Medical Device Nomenclature Code)		<b>37251</b> SURGICAL DRILLING SYSTEM
<b>UMDNS</b> (Universal Medical Device. Nomenclature System Code)		.....
<b>APPLICABLE STANDARD E DIRECTIVES</b>		
<b>Directives:</b>	<b>Medical Devices:</b> Dir. 93/42/EEC as modified Dir. 2007/47/EEC <b>Machines:</b> Dir. 2006/42/EEC	
<b>Standards:</b>	<b>Electrical safety:</b> EN 60601-1; EN60601-1-6; IEC 62304; IEC 62366 <b>Electromagnetic compatibility:</b> es. EN60601-1-2	
<b>HOMOLOGATIONS-APPROVALS</b>		
CE 0051 Certifications – Notified Body IMQ – certificato CE n°874/MDD		
<b>PRESERVATION</b>		
<b>Sterility:</b>	Non sterile DM	
<b>Sterilization method:</b>	Non sterile DM	
<b>expiry:</b>	Non sterile DM	
<b>INSTALLATION</b>		
<b>Installation area:</b>	Installation on a table / cart, far from heat sources	
<b>Ambient parameters</b>	<b>Temperature:</b> from 5 to 40°C <b>Humidity:</b> less tha 90%	
<b>Electrical connection</b>	With removable supply cable	
<b>Alimentazione UPS</b>	User's discretion according to the safety procedures in use at user facility.	
<b>Gas network connections</b>	NON necessary	
<b>Water supply Connection</b>	NON necessary	
<b>Connection data</b>	NON necessary	
<b>MANTAINANCE</b>		
<p>The device is maintenance free. The only routine maintenance IN charge to the user are:</p> <ul style="list-style-type: none"> <li>• Cleaning, disinfecting and sterilizing the handpiece and tips <ul style="list-style-type: none"> <li>• Cleaning and disinfection console</li> <li>• Replace tubing and cooling solution</li> </ul> </li> </ul> <p><b>The manner in which these activities are to be made are shown in the user manual</b>  <b>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</b></p>		

**DISPOSAL**

**For the EU territory:** According to European Directive 65/2011 / EU and transposed into national legislation Disposal of EEE

**EU Extra:** respect national rules on the disposal of electronic equipment for medical use

**STANDARD EQUIPMENT**
**Descrizione**


Id.	Componente
1	Consolle complete of peristaltic pump
2	Ultrasonic Handpiece (piezo)with cable
3	Metal bar for cooling liquid
4	Handpiece holder
5	Pneumatic pedal
6	Torque wrench
7	Manuale d'uso

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


SURGYSONIC II 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**

Consolle ; 2 Years Ultrasonic Handpiece (piezo) with cable : 1 year