

### 1. MANUFACTURER DETAILS


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### 2. CERTIFICATION DETAILS

<b>Certificate number:</b>	012/MDR Medical Device Regulation UE 2017/745 MDR
<b>Notified Body:</b>	ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Marco Fabio Quintiliano, n. 43, 20138 Milano Italy - 0051
<b>CND code(s):</b>	64187 (GNDN code)
<b>Class:</b>	Ila
<b>Classification rule:</b>	5 (Medical Device Regulation UE 2017/745 MDR)
<b>Expiry date certificate:</b>	28/09/2026
<b>Novel product:</b>	<input type="checkbox"/> yes x no

### 3. MEDICAL DEVICE DETAILS

<b>Product or trade name:</b>	SILVERPLUG
<b>General description of the device:</b>	A small device intended to plug the hole in a screw-retained crown or dental prosthesis abutment to prevent the penetration of cement, filling material or bacteria into the free space above the screw.
<b>Intended purpose:</b>	The device is intended to be used to maintain impervious a cavity of the dental prosthetic system in a tooth, preventing the penetration of cement, filling material (provisional or final) and preventing that bacteria colonize the free space and migrate towards the tissues.
<b>Intended users:</b>	Dentist (Only Doctors)
<b>Basic UDI:</b>	76401298102842G
<b>Intended patient population:</b>	Patient with a dental implant
<b>Medical condition(s):</b>	Prevention of Periimplantitis
<b>Indications:</b>	Patients with implants, to prevents the penetration of cement or filling material in the implant, thus avoiding bacterial colonization of free space and subsequent migration towards the tissues.
<b>Instruction for use:</b>	The device SILVER PLUG fits with all the type and dimension of abutment. It is necessary to cut the device to a perfect fit with the screw tunnel. The medical personnel must use SILVERPLUG according to the following instruction for use:

	<ol style="list-style-type: none"> <li>1) Implant disinfection.</li> <li>2) Abutment disinfection.</li> <li>3) Take the device out of the packaging using a dental tweezer. Place the device in the hollow seat and measure the necessary length of the SILVERPLUG in order to make it fit into the screw tunnel.</li> <li>4) Cut SILVERPLUG using dental scissors.</li> <li>5) Insert SILVERPLUG.</li> <li>6) Check the correct insertion of SILVERPLUG in site.</li> <li>7) Seal with composite.</li> </ol>
<b>Contraindications:</b>	There are no contraindications for the use of SILVERPLUG, it can be use with all the implants.
<b>Warnings:</b>	<p>Don't use SilverPlug if the packaging is open or damaged. For single use only, please do not re-use the device in order to avoid possible contamination or lack of effectiveness.</p> <p>After opening the blister packaging, SilverPlug must be used immediately.</p> <p>Keep SilverPlug away from children.</p> <p>SilverPlug is intended to be used only by trained medical personnel in suitable locations, namely dental laboratories and clinics.</p>
<b>List and description of any variants and/or packaging:</b>	<p>SilverPlug Box ( 20 pz : 2 blister of 10 pcs )</p> <p>SilverPlug mono-dose ( 1 pz )</p>
<b>List of any accessories:</b>	NA
<b>Expected lifetime of the Medical Device:</b>	No expiry.
<b>Sterilization:</b>	<p>SilverPlug is not a sterile device.</p> <p>No sterilization needed before the use.</p>
<b>Single use/reusable:</b>	SilverPlug is a single-use device.
<b>Structure:</b>	<p>SilverPlug is a preformed solid body, in the shape of a truncated cone stretched to be able to fit into the housing seat longitudinal to an implant (see figure below).</p> 
<b>Raw Materials:</b>	<ul style="list-style-type: none"> <li>- Thermo Plastic Elastomer (TPE)</li> <li>- Silver Zeolite</li> </ul>
<b>Interactions:</b>	<p>No interaction reported.</p> <p>SilverPlug must be placed in a dental prosthetic system. It is not in contact with the mucosal membranes of the body.</p>