

DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY

La sottoscritta TECRES S.p.A., con sede in Via Andrea Doria, 6 – 37066 Sommacampagna (VR) – Italy, dichiara sotto la sua responsabilità che i dispositivi nella lista allegata sono conformi ai requisiti riportati nella Direttiva Dispositivi Medici 93/42/CEE e successive modifiche.

Dichiariamo inoltre che BSI (numero di identificazione 2797) è stato nominato come nostro Organismo Notificato ad intraprendere le disposizioni di cui all'Allegato II, esclusa sezione 4, della Direttiva Dispositivi Medici.

We, TECRES S.p.A., located in Via Andrea Doria, 6 – 37066 Sommacampagna (VR) – Italy, hereby declare under our sole responsibility that the devices listed on the attached schedule conform with the appropriate requirements of the Medical Devices Directive 93/42/EEC and amendments.

We further declare that BSI (identification number 2797) is appointed as our Notified Body to undertake the provision of Annex II excluding section 4 of the Medical Devices Directive.

Data/Date: 10/02/2020



Renzo Soffiatti

Direttore Tecnico / Technical Director

Tecres S.p.A.

TECRES S.P.A.

CODE	DESCRIPTION	GMDN code	CLASS
<i>Bone cements</i>			
1200/A	CEMEX RX	35217	IIb
1200/I	CEMEX ISOPLASTIC	35217	IIb
1220/I	CEMEX ISOPLASTIC ½ PACK	35217	IIb
1200/S	CEMEX XL	35217	IIb
12A3000	CEMEX FAST	35217	IIb
1310/S	CEMEX SYSTEM 60 g	45253	IIb
1500/S	CEMEX SYSTEM 80 g	45253	IIb
13A2020	CEMEX SYSTEM FAST 40 g	45253	IIb
1510/S	CEMEX SYSTEM FAST 70 g	45253	IIb
13A2320	CEMEX SYSTEM FAST ID GREEN	45253	IIb
<i>Acrylic resins for spinal augmentation procedures (vertebroplasty, kyphoplasty) and screw augmentation</i>			
1230	MENDEC SPINE	35217	IIb
13C2000	MENDEC SPINE KIT	45253	IIb
13C2040	MENDEC SPINE HV SYSTEM	45253	IIb
13C2050	MENDEC SPINE MV SYSTEM	45253	IIb
13A2010	THE LOCKER	35217	IIb
<i>Bone cement accessories: Prep Kit with cement restrictors and Cement restrictors)</i>			
KIT-01	CEMEX PREP KIT	45253	IIb
TPA-18	CEMENT RESTRICTOR (12-18 mm) + INSERTER	38799	IIb
TPA-24	CEMENT RESTRICTOR (18-24 mm) + INSERTER	38799	IIb
<i>Bone cement / Acrylic Resins / Bone Void Filler accessories: Femoral sponge, Femoral brush, Pressurizer, Cannula, Mixing/Extrusion devices and Bone injection needles</i>			
TMP-08	FEMORAL SPONGE	47738	IIa
SPZ-01	FEMORAL BRUSH	47690	IIa
PRZ-01	CEMENT PRESSURIZER	46031	IIa
CNL-09	CANNULA 9 mm	47737	IIa
ASA0010	CANNULA FOR KNEE	47737	IIa
ASA0050	CANNULA 12 240	47737	IIa
ASA0150	CANNULA 12 180	47737	IIa
ASA0000	ACETABULUM CANNULA	47737	IIa
ASA0320	2MIX BONE CEMENT MIXER	42982	IIa
ASD0000	CANNULAE EXTRALONG 11 Gauge, 525 mm	60478	IIa
ASA0390	XTRUDER	45253	IIa
SPN0915	BONE INJECTION NEEDLE diamond tip 9 Gauge 150 mm, plastic handgrip	60478	IIa
SPN1112	BONE INJECTION NEEDLE diamond tip 11 Gauge 120 mm, plastic handgrip	60478	IIa
SPN1312	BONE INJECTION NEEDLE diamond tip 13 Gauge 120 mm, plastic handgrip	60478	IIa
SPN1512	BONE INJECTION NEEDLE diamond tip 15 Gauge 120 mm, plastic handgrip	60478	IIa
ASB0000	BONE INJECTION NEEDLE beveled tip 9 Gauge 150 mm, plastic handgrip	60478	IIa

CODE	DESCRIPTION	GMDN code	CLASS
ASB0010	BONE INJECTION NEEDLE beveled tip 11 Gauge 120 mm, plastic handgrip	60478	Ila
ASB0020	BONE INJECTION NEEDLE beveled tip 13 Gauge 120 mm, plastic handgrip	60478	Ila
ASB0120	BONE INJECTION NEEDLE beveled tip 15 Gauge 120 mm, plastic handgrip	60478	Ila
ASB0080	BONE INJECTION NEEDLE beveled tip 9 Gauge 150 mm, metal handgrip	60478	Ila
ASB0090	BONE INJECTION NEEDLE beveled tip 11 Gauge 120 mm, metal handgrip	60478	Ila
ASB0100	BONE INJECTION NEEDLE beveled tip 13 Gauge 120 mm, metal handgrip	60478	Ila
ASB0110	BONE INJECTION NEEDLE beveled tip 15 Gauge 120 mm, metal handgrip	60478	Ila
Endorthesis Screws			
01014	Titanium Endorthesis Screw (10mm)	46646	Ilb
01015	Titanium Endorthesis Screw (15mm)	46646	Ilb
01016	Titanium Endorthesis Screw (20mm)	46646	Ilb
01017	Titanium Endorthesis Screw (25mm)	46646	Ilb
01024	Conical Titanium Endorthesis Screw (0mm)	46646	Ilb
01025	Conical Titanium Endorthesis Screw (2mm)	46646	Ilb
01026	Conical Titanium Endorthesis Screw (4mm)	46646	Ilb
01027	Conical Titanium Endorthesis Screw (6mm)	46646	Ilb
Trials for: spacers, endorthesis screws			
Trials for Spacer for Hip			
SPG03	TRIAL SPACER G	44760	Ila
SPG03XL	TRIAL SPACER G XL	44760	Ila
SPC90Z0	SPACER G FLAT TRIAL	44760	Ila
SPC91Z0	SPACER G FLAT XL TRIAL	44760	Ila
Trials for Spacer for Knee			
SPK03	TRIAL SPACER K	44760	Ila
SPK03Z0	SPACER K TRIAL XL	44760	Ila
Trials for Spacer for Shoulder			
SPS90Z0	SPACER-S TRIAL	44760	Ila
Trials for Endorthesis Screws			
01CZ0Z0	TRIAL SCREWS SET	44760	Ila
Cemover and its accessory 8mm Drill			
EXA0030	METAL CEMOVER 120 mm	58885	Ila
EXA0040	METAL CEMOVER 150 mm	58885	Ila
EXA0050	METAL CEMOVER 180 mm	58885	Ila
ASA0190	8-mm DRILL	58885	Ila
Bone cement / Acrylic Resins accessories: Bowl & Spatula, Cemex System Container, Mixing/Extrusion/Delivery devices, Freezer Ring, Manifold, Connection tubes, Mendec Aqua			
CPSP-02	BOWL AND SPATULA	36000	Is
ASA0030	CEMEX SYSTEM CONTAINER	47741	Is
ASA0380	SHAKIT	45253	Is

CODE	DESCRIPTION	GMDN code	CLASS
ASB0050	FREEZER RING	47740	Is
ASC0000	MENDEC V FILL	45253	Is
ASB0250	HP CONNECTION TUBE	45253	Is
ASC0020	MENDEC AQUA	45253	Is
ASC0030	MENDEC AQUA CARTRIDGE	45253	Is
Templates for Spacers			
B1L001	TEMPLATE SPACER-G	46479	Im
B1L002	TEMPLATE SPACER-G XL	46479	Im
B1L003	TEMPLATE SPACER-K	46479	Im
B1L008	TEMPLATE SPACER-S	46479	Im
B1L009	TEMPLATE SPACER-G FLAT	46479	Im
B1L010	TEMPLATE SPACER-G FLAT XL	46479	Im