

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 sui dispositivi medici 93/42/CEE e successive modifiche.

Dichiariamo inoltre che BSI (numero di identificazione 2797) è stata nominato come nostro Organismo Notificato ad intraprendere le disposizioni di cui all'Allegato II, Sezioni 3 e 4 della Direttiva.

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, Sections 3 and 4 of the Directive.

Data/Date: 11/10/2019



Renzo Soffiatti

Direttore Tecnico / Technical Director

Tecres S.p.A.

TECRES S.p.A.

Via Andrea Doria, 6 – 37066 Sommacampagna (VR) – Italy
T +39 045 9217311 – F +39 045 9217330 – www.tecres.it
Cap.Soc. euro 850.000,00 i.v. – C.F. e Reg. Imprese VR 01346810235
P.IVA 02042700233 – REA n° 211053 – Società a socio unico
soggetta ad attività di direzione e coordinamento di Demetra Holding S.p.A.

CODE	DESCRIPTION	GMDN code	CLASS
Bone cement with Gentamicin			
1400/AG	CEMEX GENTA Low Viscosity	46059	III
1400/IG	CEMEX GENTA High Viscosity	46059	III
12A3100	CEMEX GENTA FAST	46059	III
1400/AG INT	CEMEX GENTA LV GAMMA	46059	III
1400/IG INT	CEMEX GENTA HV GAMMA	46059	III
12A2420	CEMEX GENTA ID GREEN	46059	III
1310/SG	CEMEX GENTA SYSTEM 60 g	45253	III
1500/SG	CEMEX GENTA SYSTEM 80 g	45253	III
13A2100	CEMEX SYSTEM GENTA FAST 70g	45253	III
13A2110	CEMEX SYSTEM GENTA FAST 40g	45253	III
13A2420	CEMEX SYSTEM GENTA ID GREEN 70g	45253	III
Bone cement with Gentamicin and Vancomycin			
12A2520	VANCOGENX	46059	III
12A2530	VANCOGENX HV	46059	III
Spacer with Gentamicin			
Spacer for Hip			
SPC46/G	SPACER-G 46	33982	III
SPC54/G	SPACER-G 54	33982	III
SPC60/G	SPACER-G 60	33982	III
SPC46/GXL	SPACER-G 46 XL	33982	III
SPC54/GXL	SPACER-G 54 XL	33982	III
SPC60/GXL	SPACER-G 60 XL	33982	III
SPC0620	SPACER-G FLAT 46	33982	III
SPC0720	SPACER-G FLAT 54	33982	III
SPC0820	SPACER-G FLAT 60	33982	III
SPC0920	SPACER-G FLAT 46 XL	33982	III
SPC1020	SPACER-G FLAT 54 XL	33982	III
SPC1120	SPACER-G FLAT 60 XL	33982	III
Spacer for Knee			
SPK6054/G	SPACER-K 6054	33982	III
SPK7064/G	SPACER-K 7064	33982	III
SPK8074/G	SPACER-K 8074	33982	III
Spacer for Shoulder			
SPS0020	Spacer-S 41	33982	III
SPS46/G	Spacer-S 46	33982	III
Spacer with Gentamicin and Vancomycin			
Spacer for Hip			
SPC0030	VANCOGENX-SPACE HIP 46	33982	III
SPC0130	VANCOGENX-SPACE HIP 54	33982	III
SPC0230	VANCOGENX-SPACE HIP 60	33982	III
SPC0330	VANCOGENX-SPACE HIP 46XL	33982	III
SPC0430	VANCOGENX-SPACE HIP 54XL	33982	III

CODE	DESCRIPTION	GMDN code	CLASS
SPC0530	VANCOGENX-SPACE HIP 60XL	33982	III
SPC0630	VANCOGENX-SPACE HIP FLAT STEM 46	33982	III
SPC0730	VANCOGENX-SPACE HIP FLAT STEM 54	33982	III
SPC0830	VANCOGENX-SPACE HIP FLAT STEM 60	33982	III
SPC0930	VANCOGENX-SPACE HIP FLAT STEM 46XL	33982	III
SPC1030	VANCOGENX-SPACE HIP FLAT STEM 54XL	33982	III
SPC1130	VANCOGENX-SPACE HIP FLAT STEM 60XL	33982	III
Spacer for Knee			
SPK0030	VANCOGENX-SPACE KNEE 6054	33982	III
SPK0130	VANCOGENX-SPACE KNEE 7064	33982	III
SPK0230	VANCOGENX-SPACE KNEE 8074	33982	III
SPK0330	VANCOGENX-SPACE KNEE 9084	33982	III
Acrylic Resin for Cranioplasty			
1220/D	MENDEC CRANIO (radiopaque)	16131	III
Bone Void Filler			
13A6000	CAL-CEMEX	17751	III
Bone cements			
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
Acrylic resins for spinal augmentation procedures (vertebroplasty, kyphoplasty) and screw augmentation			
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
Bone cement accessories: Prep Kit with cement restrictors and Cement restrictors)			
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
Bone cement / Acrylic Resins / Bone Void Filler accessories: Femoral sponge, Femoral brush, Pressurizer, Cannula, Mixing/Extrusion devices and Bone injection needles			
TMP-08	FEMORAL SPONGE	47738	IIa
SPZ-01	FEMORAL BRUSH	47690	IIa
PRZ-01	CEMENT PRESSURIZER	46031	IIa

CODE	DESCRIPTION	GMDN code	CLASS
CNL-09	CANNULA 9 mm	47737	Ila
ASA0010	CANNULA FOR KNEE	47737	Ila
ASA0050	CANNULA 12 240	47737	Ila
ASA0150	CANNULA 12 180	47737	Ila
ASA0000	ACETABULUM CANNULA	47737	Ila
ASA0320	2MIX BONE CEMENT MIXER	42982	Ila
ASD0000	CANNULAE EXTRALONG 11 Gauge, 525 mm	60478	Ila
ASA0390	XTRUDER	45253	Ila
SPN0915	BONE INJECTION NEEDLE diamond tip 9 Gauge 150 mm, plastic handgrip	60478	Ila
SPN1112	BONE INJECTION NEEDLE diamond tip 11 Gauge 120 mm, plastic handgrip	60478	Ila
SPN1312	BONE INJECTION NEEDLE diamond tip 13 Gauge 120 mm, plastic handgrip	60478	Ila
SPN1512	BONE INJECTION NEEDLE diamond tip 15 Gauge 120 mm, plastic handgrip	60478	Ila
ASB0000	BONE INJECTION NEEDLE beveled tip 9 Gauge 150 mm, plastic handgrip	60478	Ila
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

CODE	DESCRIPTION	GMDN code	CLASS
<i>Trials for Spacer for Knee</i>			
SPK03	TRIAL SPACER K	44760	Ila
SPK03Z0	SPACER K TRIAL XL	44760	Ila
<i>Trials for Spacer for Shoulder</i>			
SPS90Z0	SPACER-S TRIAL	44760	Ila
<i>Trials for Endorthesis Screws</i>			
01CZ0Z0	TRIAL SCREWS SET	44760	Ila
<i>Cemover and its accessory 8mm Drill</i>			
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
<i>Bone cement / Acrylic Resins accessories: Bowl & Spatula, Cemex System Container, Mixing/Extrusion/Delivery devices, Freezer Ring, Manifold, Connection tubes, Mendec Aqua</i>			
CPSP-02	BOWL AND SPATULA	36000	Is
ASA0030	CEMEX SYSTEM CONTAINER	47741	Is
ASA0380	SHAKIT	45253	Is
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
<i>Templates for Spacers</i>			
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