

DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY

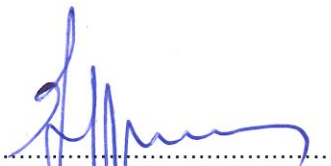
La sottoscritta TECRES S.p.A., con sede in Via Andrea Doria, 6 – 37066 Sommacampagna (VR) – Italy, dichiara sotto la sua responsabilità che i dispositivi nella lista allegata sono conformi ai requisiti riportati nella Direttiva Dispositivi Medici 93/42/CEE e successive modifiche.

Dichiariamo inoltre che BSI (numero di identificazione 2797) è stato nominato come nostro Organismo Notificato ad intraprendere le disposizioni di cui all'Allegato II, inclusa 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 including section 4 of the Medical Devices Directive.

Data/Date: 29/04/2021



Giuseppe Gazzara
Technical Director
Tecres S.p.A.

TECRES S.P.A.

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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
<i>Bone cement with Gentamicin</i>			
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
<i>Bone cement with Gentamicin and Vancomycin</i>			
12A2520	VANCOGENX	46059	III
12A2530	VANCOGENX HV	46059	III
<i>Spacer with Gentamicin</i>			
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
SPK0420	Spacer-K ATS 60/07	33982	III
SPK0520	Spacer-K ATS 60/12	33982	III
SPK0620	Spacer-K ATS 80/07	33982	III
SPK0720	Spacer-K ATS 80/12	33982	III
Spacer for Shoulder			
SPS0020	Spacer-S 41	33982	III
SPS46/G	Spacer-S 46	33982	III
<i>Spacer with Gentamicin and Vancomycin</i>			
Spacer for Hip			
SPC0030	VANCOGENX-SPACE HIP 46	33982	III
SPC0130	VANCOGENX-SPACE HIP 54	33982	III

CODE	DESCRIPTION	GMDN code	CLASS
SPC0230	VANCOGENX-SPACE HIP 60	33982	III
SPC0330	VANCOGENX-SPACE HIP 46XL	33982	III
SPC0430	VANCOGENX-SPACE HIP 54XL	33982	III
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
SPK0430	Vancogenx-Space Knee ATS 60/07	33982	III
SPK0530	Vancogenx-Space Knee ATS 60/12	33982	III
SPK0630	Vancogenx-Space Knee ATS 80/07	33982	III
SPK0730	Vancogenx-Space Knee ATS 80/12	33982	III
Acrylic Resin for Cranioplasty			
1220/D	MENDEC CRANIO (radiopaque)	16131	III
Bone Void Filler			
13A6000	CAL-CEMEX	17751	III