

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 738034 R000

Manufacturer: Tecres S.p.A.

Address:

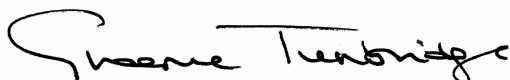
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

Single Registration Number: IT-MF-000027512

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-05-10**

Current Issue Date: **2023-01-17**

Starting Validity Date: **2023-01-17**

Expiry Date: **2026-05-09**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Orthopaedic prostheses cement incorporating Gentamycin as ancillary substances– RALLY™ AB Bone Cement	See MDR 739359
Orthopaedic prostheses cement incorporating Gentamycin as ancillary substances and application devices –RALLY™ AB all in One System	See MDR 739359
Orthopaedic prostheses cement incorporating Gentamycin as ancillary substances– Cemex Genta, MectaCem-X with Gentamicin, Conflow G bone cement	See MDR 738112
Orthopaedic prostheses cement incorporating Gentamycin as ancillary substances and application devices–Cemex System Genta	See MDR 738112
Orthopaedic prostheses cement incorporating Gentamycin and Vancomycin as ancillary substances – Vancogenx, GV Cement	See MDR 738100
Temporary knee prosthesis incorporating Gentamycin as ancillary substances – Spacer-K and Spacer-K ATS	See MDR 738104
Temporary hip prosthesis incorporating Gentamycin as ancillary substances – Spacer-G	See MDR 738108
Temporary knee prosthesis incorporating Gentamycin as ancillary substances - Spacer-S	See MDR 739361
Temporary hip prosthesis incorporating Gentamycin and Vancomycin as ancillary substances – Vancogenx Space Hip	See MDR 739363

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cranial implant including those incorporating antibiotic(s) as ancillary substance(s)	Custom-made Class III Implantable

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-05-10	3310730	Issued.
Current	3756075	Amended – Addition of SRN number. Amended – Addition of subcontractor for sterilization by radiation (Gamma Sterilization) Supplemented – Addition of class III implantable device groups "Rally AB Bone Cement", "RALLY™ AB all in One System", "Cemex Genta", "MectaCem-X with Gentamicin", "Conflow G bone cement", "Cemex System Genta", "Vancogenx", "GV Cement", "Spacer K", "Spacer-K ATS", "Spacer G", "Spacer S" and "Vancogenx Space Hip".

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