

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Tecres S.p.A.
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

Holds Certificate Number:

MD 641428

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of bone cements and associated products, orthopaedic screws and implants. Manufacture of metal finishing and labelling. Distribution of medical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-05-31

Latest Revision Date: 2021-02-18

Effective Date: 2021-02-27

Expiry Date: 2024-02-26

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 738112 R000

Manufacturer: Tecres S.p.A.

Address:

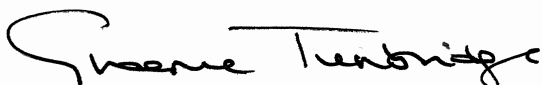
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

Single Registration Number: IT-MF-000027512

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2023-01-17**

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

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

Expiry Date: **2028-01-16**

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Device Schedule:

Intended Purpose as per the Instructions for Use: Orthopedic cement incorporating Gentamycin as ancillary substances intended for fixation of joint prosthesis (hip, knee) implants to the host bone.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDN 1102

Basic UDI-DI	Ref. Code	Trade Name	Description
80314970111N8	1400/AG	Cemex Genta Low Viscosity	40g - Low viscosity –Standard setting – powder sterilized EtO
	1400/IG	Cemex Genta High Viscosity	40g - High viscosity –Standard setting - powder sterilized EtO
	12A3100	Cemex Genta Fast	2x 20g - High viscosity –Fast setting - powder sterilized Gamma
	12A2400	Cemex Genta ID LV	40g - Low viscosity –Standard setting – powder sterilized EtO - green
	12A2410	Cemex Genta ID HV	40g - High viscosity –Standard setting - powder sterilized EtO-green
	12A2420	Cemex Genta ID Green	40g - Medium viscosity –Fast setting - powder sterilized gamma - green
	1400/AG INT	Cemex Genta LV Gamma	40g - Low viscosity –Standard setting - powder sterilized Gamma
	1400/IG INT	Cemex Genta HV Gamma	40g - High viscosity –Standard setting - powder sterilized Gamma

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 738112 R000

B-UDI	Ref. Code	Trade Name	Description
	110043036	Conflow G Bone Cement	40g - Low viscosity –Standard setting - powder sterilized Gamma
	65.01.100	MectaCem-X Fast with gentamicin	2x 20g - High viscosity –Fast setting - powder sterilized Gamma
	65.01.113	MectaCem-X LV with gentamicin	40g - Low viscosity –Standard setting - powder sterilized Gamma
	65.01.111	MectaCem-X HV with gentamicin	40g - High viscosity –Standard setting - powder sterilized Gamma
80314970161NP	13A2100	Cemex System Genta Fast 70g	70g - Medium viscosity –Fast setting - powder sterilized EtO
	13A2110	Cemex System Genta Fast 40g	40g - Medium viscosity –Fast setting - powder sterilized EtO
	13A2400	Cemex System ID Genta 60g	60g - Low viscosity –Standard setting – powder sterilized EtO - green
	13A2410	Cemex System ID Genta 80g	80g - Low viscosity –Standard setting – powder sterilized EtO - green
	13A2420	Cemex System Genta ID Green 70g	70g - Medium viscosity –Fast setting - powder sterilized EtO - green
	13A2430	Cemex System Genta ID Green 40g	40g - Medium viscosity –Fast setting - powder sterilized EtO - green
	1310/SG	Cemex Genta System 60g	60g - Low viscosity –Standard setting – powder sterilized EtO
	1500/SG	Cemex Genta System 80g	80g - Low viscosity –Standard setting – powder sterilized EtO

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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
Current	3311268	Issued



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

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