

# EU Technical Documentation Assessment Certificate

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

## MDR 738112 R000

**Manufacturer:** Tecres S.p.A.

**Address:**

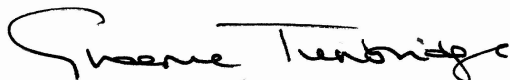
Via Andrea Doria, 6  
Sommacampagna (VR)  
37066  
Italy

**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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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



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