

EU Technical Documentation Assessment Certificate

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

MDR 738112 R000

Manufacturer: Tecres S.p.A.

Address:

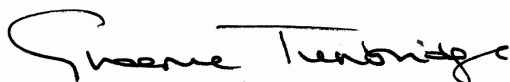
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

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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