

EC Declaration of Conformity

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

SRN: IT-MF-000027512

Basic UDI-DI:

80314970111N8

80314970161NP

Product name:

Cemex Genta

Cemex System Genta

Product codes and description: see Annex 1

Risk class: III

Intended purpose Cemex Genta are intended for the fixation of joint prosthesis (hip, knee) implants to the host bone

Common Specification(s) Not available

Notified Body: BSI Group The Netherlands B.V.
(NB 2797)

Conformity assessment route: Annex IX:
- chapter I: Quality Management system (all)
- chapter II: Assessment of technical documentation (paragraphs 4 and 5, sub-paragraph 5.1, 5.2 and 5.3.2)
- chapter III: Administrative Provisions (all)

TECRES S.P.A.

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T +39 045 9217311 - F +39 045 9217330 - www.tecres.it
Cap.Soc. euro 850.000,00 i.v. - C.F. e Reg. Imprese VR 01346810235
P.IVA 02042700233 - REA n° 211053 - Società a socio unico
soggetta ad attività di direzione e coordinamento di Demetra Holding S.p.A.

**EU Quality Management
System Certificate**

Certificate Number MDR 738034 R000
Issue Date 2021-05-10
Expiry Date 2026-05-09

**EU Technical Documentation
Assessment Certificate**

Certificate Number MDR 738112 R000
Issue Date 2023-01-17
Expiry Date 2028-01-16

This declaration of conformity is issued under the sole responsibility of the manufacturer. We hereby declare that the medical device(s) listed meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Place and date (yyyy-mm-dd) of issue:

Sommacampagna, 2023-01-19

Signature:

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Giuseppe Gazzara
Technical Director

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Annex 1

Ref. Code	Trade Name
1400/AG	Cemex Genta Low Viscosity
1400/IG	Cemex Genta High Viscosity
12A3100	Cemex Genta Fast
1310/SG	Cemex Genta System 60g
1500/SG	Cemex Genta System 80g
13A2100	Cemex System Genta Fast 70g
13A2110	Cemex System Genta Fast 40g
12A2400	Cemex Genta ID LV
12A2410	Cemex Genta ID HV
12A2420	Cemex Genta ID Green
13A2400	Cemex System ID Genta 60g
13A2410	Cemex System ID Genta 80g
13A2420	Cemex System Genta ID Green 70g
13A2430	Cemex System Genta ID Green 40g
1400/AG INT	Cemex Genta LV Gamma
1400/IG INT	Cemex Genta HV Gamma

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