

EC Declaration of Conformity

Manufacturer:	Tecres S.p.A. Via Andrea Doria, 6 Sommacampagna (VR) 37066 Italy
SRN:	IT-MF-000027512
Basic UDI-DI:	80314970142NK
Product name:	Vancogenx
Product codes and description:	see Annex 1
Risk class:	III
Intended purpose	VANCOGENX bone cements are indicated for: a) temporary fixation of PMMA antibiotic-loaded spacer for two-stage procedure; b) permanent fixation of joint prosthesis implants (hip, knee) to the host bone following a two-stage procedure due to a septic process.
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)

**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 738100 R000
Issue Date 2023-01-17
Expiry Date 2028-01-16

TECRES S.P.A.

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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.

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, 2023-01-20

Signature:

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Giuseppe Gazzara
Technical Director

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Annex 1

Ref. Code	Trade Name
12A2520	Vancogenx
12A2530	Vancogenx HV
12A2522	GV Cement
12A2531	GV Cement HV

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