

EU Technical Documentation Assessment Certificate

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

MDR 738100 R000

Manufacturer: Tecres S.p.A.

Address:

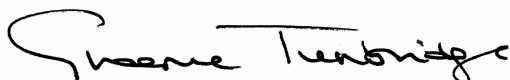
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

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:

Vancogenx bone cements are intended for temporary fixation of PMMA antibiotic-loaded spacer for two-stage procedure or permanent fixation of joint prosthesis implants (hip, knee) to the host bone following a two-stage procedure due to a septic process.

Risk Classification: Class III Implantable

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

Basic UDI-DI: 80314970142NK

Device Name	Model	Viscosity	Brand Name
Vancogenx	12A2520	Medium	Vancogenx Bone Cements
Vancogenix HV	12A2530	High	Vancogenx Bone Cements
GV Cement	12A2522	Medium	Vancogenx Bone Cements
GV Cement HV	12A2531	High	Vancogenx Bone Cements

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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	3311164	Issued

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