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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719475 R000

Manufacturer: TEKNIMED SAS

Address:

8 rue du Corps Franc Pommiès Vic-en-Bigorre 65500 France

Single Registration Number: FR-MF-000001224

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II 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: 2021-12-22

Current Issue Date: 2022-11-09

Starting Validity Date: 2022-11-09

Expiry Date: 2026-12-21

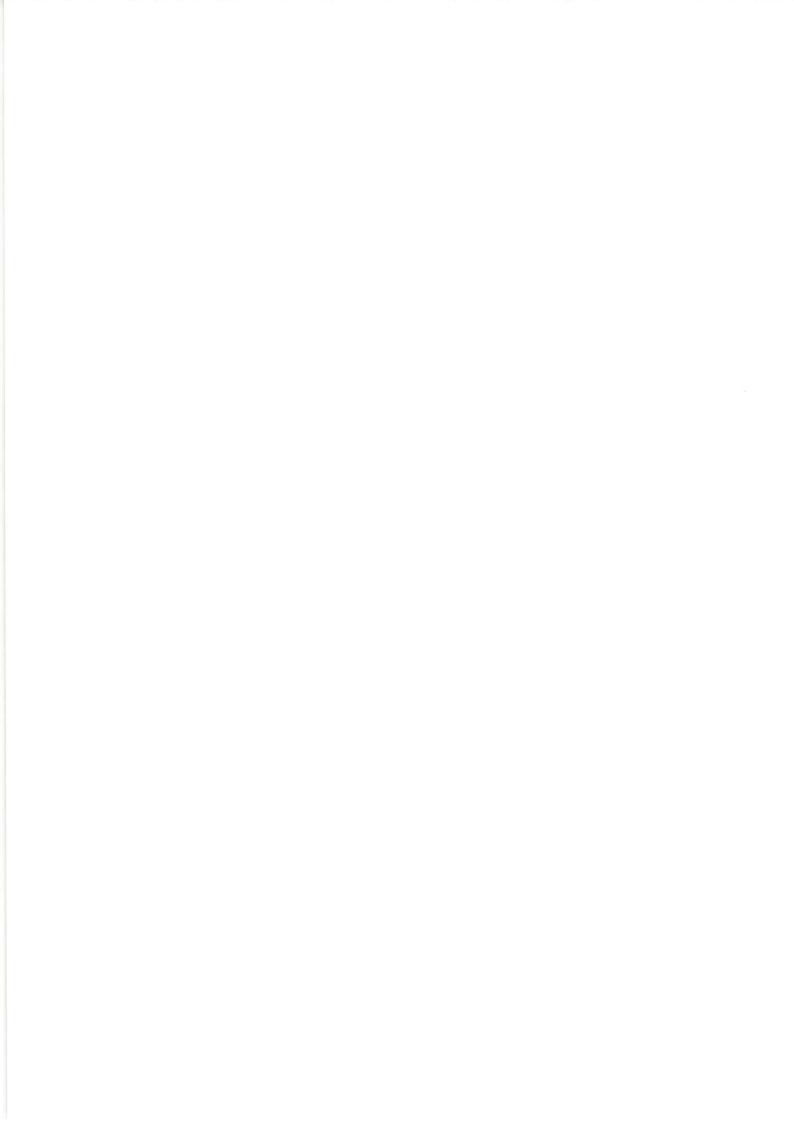
...making excellence a habit."

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.



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Device Schedule: Class III devices and Class IIb Devices

Class III, Implantable	Intended purpose		
Bioabsorbable cement restrictor – CEMSTOP, CLEARCUT, ESOBLOCK, QUIRURFIX, MECTAPLUG, NEPTUNPLUG, CemP, Tekstop, ic cement restrictor resorbable, B-Plug, CPS Plug	See MDR 736238	9. 9.	
Synthetic bone substitutes – CERAFORM, HYDROSUB	See MDR 737951		
Bone cements with gentamicin — GENTAFIX, AMPLIFIX G, BezGen, BIOGENT, CM-PX G, DYNABONE G, EVOCEM G, IMPLABOND G, NexCem G, OPTICEM G, ORCEM G, PALAFOM GENTA, PERFIX PLUS G, ProstheSet, ROYAL CEMENT, SINPLUS G, ArthroCem G, C-fix G, GentaCem, Jointfix G, ORTHOCEM G, Prosthefix G, TEKCEM G, Signature-X cement, Synth-X	See MDR 736239		

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	
Orthopaedic cement preparation and application devices and kits	Class Is	

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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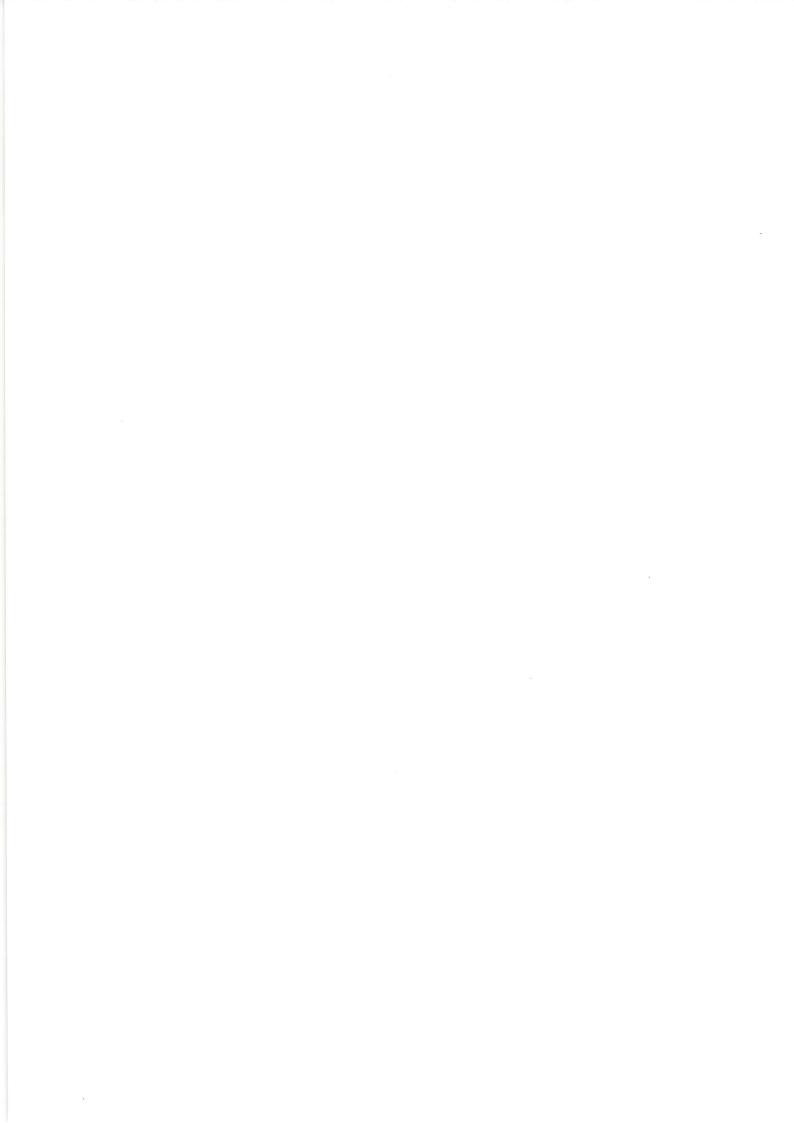
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Certificate History

Asserting the Applicable Common Specifications, Harmonized Standards compiled with, and the relevant test and audit reports that support and the basis certificate changes may be requested from Certificate. Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-22	3090169	Issued
2022-06-17	3698487	Amended – Approval of subcontractors Supplemented – addition of Orthopaedic cement preparation and application devices and kits
2022-07-21	3729814	Supplemented - Addition of synthetic bone substitutes CERAFORM and HYDROSUB.
Current	3773095	Supplemented – Addition of bone cements with gentamicin – GENTAFIX, AMPLIFIX G, BezGen, BIOGENT, CM-PX G, DYNABONE G, EVOCEM G, IMPLABOND G, NexCem G, OPTICEM G, ORCEM G, PALAFOM GENTA, PERFIX PLUS G, ProstheSet, ROYAL CEMENT, SINPLUS G, ArthroCem G, C-fix G, GentaCem, Jointfix G, ORTHOCEM G, Prosthefix G, TEKCEM G, Signature-X cement, Synth-X Amended - Administrative updates to previous history entry 3698487

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