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By Royal Charter

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

Digitally signed by Cobzari-Turcan Rodica
Date: 2023.03.16 09:20:31 EET
Reason: MoldSign Signature
Location: Moldova

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**

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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
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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Certificate History

(reference 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
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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