

EU Quality Management System Certificate

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

MDR 719475 R000

Manufacturer: TEKNIMED SAS

Address:

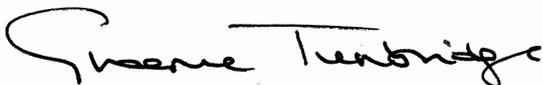
8 rue du Corps Franc Pomiès
Vic-en-Bigorre
65500
France

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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: **2024-03-20**

Starting Validity Date: **2024-03-20**

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
Synthetic bone substitute with nanomaterials - NANOGEL®, MECTAGEL, NEVE, OptiFuse, OSTIBONE, Nanotek, IB Fluid, Teknigel, Cgel, B-Paste	See MDR 737953
Low viscosity radiopaque bone cement - Spine-Fix®, MVX, Vertefix Plus, Vertocure LVHA+, SPONDY FX, SPF 1, HPMIX +, ONCO 10, LVM+, AVECEM, P-CEM, FIX C	See MDR 737972
Medium viscosity radiopaque bone cement - F20®, OPTICEM SPINE, SINPLUS S, OSTEOFLEX, VERTOCURE, FRX-CMT, OSTEOFIX, MVX+, VERTERO, MV CEM, K CEM, META+, POLYCEM, OSTEO+, VERTEB 24, Z4+, STR 12, X CEM, CMV, Invictus™ Bone cement	See MDR 737974
High viscosity radiopaque bone cements - HIGHV +, LUCENCE, FLEX 24, HACEM+, HV 1300, CEM 56, HGTV+, VHCEM, H-CEM, N Gold, NEO V+, VV+, Nuvasive Maximum Viscosity Cement, INTROX High V.	See MDR 737975
Low viscosity radiopaque bone cements - OPACITY+, OSSEOFIX +, EXOFIX, OSTEOFLEX LV, THERMALFIX, Synth-X SL, Merit Fastrak, LV 45, 12,5 CEM, ZR+, BLACK C, SAFE CEM, OPT 15, PMM+.	See MDR 737976
Bio-absorbable osteosynthesis implants, TLS Bio-C®	See MDR 737970
Bio-absorbable osteosynthesis implants, ISOFIX+®	See MDR 737968

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Class IIb, Implantable, Well-established technologies Suture – Tendons and Ligaments reintegration	Intended purpose Intended for repairing or reinforcing ligaments, closure and/or ligation of soft tissues, and tuberosity reinsertions
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Class IIb non-WET, Implantable High and Low Viscosity Surgical Cements: CEMFIX® 1 , CEMFIX® 3, AMPLIFIX 1, AMPLIFIX 3, BIOCEMIUM I, BIOCEMIUM III, IMPLABOND 1, IMPLABOND 3, OPTICEM 1, OPTICEM 3, ORCEM 1, ORCEM 3, PALAFOM 1, PALAFOM 3, SINPLUS 1, SINPLUS 3, ORTHOCEM 1, ORTHOCEM 3, EVOCEM 1, EVOCEM 3, NexCem 1, NexCem 3, Signature Cement SV, Signature Cement LV, ProstheSet 13, ProstheSet 14, PERFIX PLUS 1, PERFIX PLUS 3, SYNTH-X OH, SYNTH-X OL, BezCem 1, BezCem 3, CM-PX 1, CM-PX 3, Dynabone 1, Dynabone 3, TEKCEM 1, TEKCEM 3, C-Fix 1, C-Fix 3, ArthroCem 1, ArthroCem 3, Jointfix 1, Jointfix 3, Prosthefix 1, Prosthefix 3, C-Cem 1, C-Cem 3	Intended purpose See MDR 739319
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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

(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
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.
2022-11-09	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, ProtheSet, 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
2023-05-25	3817561	Supplemented – Addition of synthetic bone substitute with nanomaterials - NANOGEL®, MECTAGEL, NEVE, OptiFuse, OSTIBONE, Nanotek, IB Fluid, Teknigel, Cgel, B-Paste
2023-08-16	30001124	Supplemented – Addition of Low viscosity radiopaque bone cement - Spine-Fix®, MVX, Vertefix Plus, Vertocure LVHA+, SPONDY FX, SPF 1, HPMIX +, ONCO 10, LVM+, AVECEM, P-CEM, FIX C and Medium viscosity radiopaque bone cement - F20®, OPTICEM SPINE, SINPLUS S, OSTEOFLEX, VERTOCURE, FRX-CMT, OSTEOFIX, MVX+, VERTERO, MV CEM, K CEM, META+, POLYCEM, OSTEO+, VERTEB 24, Z4+, STR 12, X CEM, CMV, Invictus™ Bone cement

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Date	Reference Number	Action
2023-12-04	30009434	Supplemented – Addition of High viscosity radiopaque bone cements - HIGHV +, LUCENCE, FLEX 24, HACEM+, HV 1300, CEM 56, HGTV+, VHCEM, H-CEM, N Gold, NEO V+, VV+, Nuvasive Maximum Viscosity Cement, INTROX High V and Low viscosity radiopaque bone cements - OPACITY+, OSSEOFIX +, EXOFIX, OSTEOFLEX LV, THERMALFIX, Synth-X SL, Merit Fastrak, LV 45, 12,5 CEM, ZR+, BLACK C, SAFE CEM, OPT 15, PMM+.
2024-01-22	30055461	Supplemented – Addition of High and Low Viscosity Surgical Cements: CEMFIX® 1 , CEMFIX® 3, AMPLIFIX 1, AMPLIFIX 3, BIOCEMIUM I, BIOCEMIUM III, IMPLABOND 1, IMPLABOND 3, OPTICEM 1, OPTICEM 3, ORCEM 1, ORCEM 3, PALAFOM 1, PALAFOM 3, SINPLUS 1, SINPLUS 3, ORTHOCEM 1, ORTHOCEM 3, EVOCEM 1, EVOCEM 3, NexCem 1, NexCem 3, Signature Cement SV, Signature Cement LV, ProstheSet 13, ProstheSet 14, PERFIX PLUS 1, PERFIX PLUS 3, SYNTH-X OH, SYNTH-X OL, BezCem 1, BezCem 3, CM-PX 1, CM-PX 3, Dynabone 1, Dynabone 3, TEKCEM 1, TEKCEM 3, C-Fix 1, C-Fix 3, ArthroCem 1, ArthroCem 3, Jointfix 1, Jointfix 3, Prosthefix 1, Prosthefix 3, C-Cem 1, C-Cem 3
2024-02-29	30073600	Supplemented – Addition of Suture – Tendons and Ligaments reintegration and Bio-absorbable osteosynthesis implants: TLS Bio-C® Amended – Approval of subcontractors
Current	30121141	Supplemented – Addition of Bio-absorbable osteosynthesis implants: ISOFIX+®

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