EU Technical Documentation Assessment Certificate

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

MDR 736239 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 Şarco Alexandru
Date: 2024.08.17 13:55:09 EEST
Reason: MoldSign Signature
Location: Moldova

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: **2022-11-09**

Current Issue Date: **2022-11-09**

Starting Validity Date: **2022-11-09**

Expiry Date: **2027-11-08**

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Device Schedule:

Intended Purpose as per the Instructions for Use: Bone cements with gentamicin are intended for fixation of prosthetic components into bone medullar cavity in arthroplasty procedures.

Risk Classification: Class III Implantable

Basic UDI-DI: 376017704B01CS

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

Device name	Viscosity	Catalogue Number
GENTAFIX 1	High viscosity	T040140G
GENTAFIX 3	Low viscosity	T040340G
GENTAFIX 3 MV	Medium viscosity	T040341G
AMPLIFIX 1G	High viscosity	1-0400201
AMPLIFIX 3G	Low viscosity	1-0400203
BezGen 1	High viscosity	410002
BezGen 3	Low viscosity	410004
BezGen 3MV	Medium viscosity	410005
BIOGENT I	High viscosity	1 110 410 040
BIOGENT III	Low viscosity	1 110 410 045
CM-PX 1G	High viscosity	CMPX1G
CM-PX 3G	Low viscosity	CMPX3G
CM-PX 3GMV	Medium viscosity	CMPX3GMV
DYNABONE 1G	High viscosity	DYN-1G
DYNABONE 3G	Low viscosity	DYN-3G
DYNABONE 3G MV	Medium viscosity	DYN-3GMV
EVOCEM G1	High viscosity	B01 401A
EVOCEM G3	Low viscosity	B01 403A
IMPLABOND 1G	High viscosity	D041140G
IMPLABOND 3G	Low viscosity	D041340G
NexCem 1G	High viscosity	PMQ1-40G

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Device name	Viscosity	Catalogue Number
NexCem 3G	Low viscosity	PMQ3-40G
NexCem 3GMV	Medium viscosity	PMQ3-40GMV
OPTICEM 1G	High viscosity	C022
OPTICEM 3G	Low viscosity	C044
ORCEM 1G	High viscosity	17.0101
ORCEM 3G	Low viscosity	17.0102
PALAFOM GENTA 1	High viscosity	1702
PALAFOM GENTA 3	Low viscosity	1704
PALAFOM GENTA 3GMV	Medium viscosity	1705
PERFIX PLUS 1G	High viscosity	870014
PERFIX PLUS 3G	Low viscosity	870012
ProstheSet 12	High viscosity	MPBC12-T040140G
ProstheSet 11	Low viscosity	MPBC11-T040340G
ProstheSet 10	Medium viscosity	MPBC10-T040341G
ROYAL CEMENT 1GT	High viscosity	RM040140G
ROYAL CEMENT 3GT	Low viscosity	RM040340G
SINPLUS 1G	High viscosity	1015
SINPLUS 3G	Low viscosity	3015
ArthroCem 1G	High viscosity	040140GC
ArthroCem 3G	Low viscosity	040340GC
ArthroCem 3G MV	Medium viscosity	040341GC
C-fix 1G	High viscosity	040140GA
C-fix 3G	Low viscosity	040340GA
C-fix 3G MV	Medium viscosity	040341GA
GentaCem 1	High viscosity	040140GF
GentaCem 3	Low viscosity	040340GF
GentaCem 3 MV	Medium viscosity	040341GF
Jointfix 1G	High viscosity	040140GD
Jointfix 3G	Low viscosity	040340GD
Jointfix 3G MV	Medium viscosity	040341GD
ORTHOCEM 1G	High viscosity	C040140G

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Device name	Viscosity	Catalogue Number
ORTHOCEM 3G	Low viscosity	C040340G
ORTHOCEM 3G MV	Medium viscosity	C040341G
Prosthefix 1G	High viscosity	040140GE
Prosthefix 3G	Low viscosity	040340GE
Prosthefix 3G MV	Medium viscosity	040341GE
TEKCEM 1G	High viscosity	B040140G
TEKCEM 3G	Low viscosity	B040340G
TEKCEM 3G MV	Medium viscosity	B040341G
Signature-X Cement SV	High viscosity	P/N191-14-4000
Signature-X Cement LV	Low viscosity	P/N191-14-4001
Signature-X Cement MV	Medium viscosity	MVP/N191-14-4002
Synth-X OH+	High viscosity	HC-SX-OHP
Synth-X OL+	Low viscosity	HC-SX-OLP
Synth-X OM+	Medium viscosity	HC-SX-OMP

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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	3252756	Issued

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