CE

EU DECLARATION OF CONFORMITY

We,

TEKNIMED SAS

8, rue du Corps Franc Pommiès
65500 Vic-en-Bigorre
France
Single Registration Number (SRN): **FR-MF-000001224**

declare under our sole responsibility that the following medical devices:

Product Name:	**GENTAFIX®**	
Designation:	**Surgical cement with gentamicin**	
Intended purpose:	**Fixation of prosthetic components into bone medullar cavity in arthroplasty procedures**	
Reference Number and Description:	**T040140G**	**GENTAFIX® 1 - High viscosity**
	T040340G	**GENTAFIX® 3 - Low viscosity**
	T040341G	**GENTAFIX® 3MV - Medium viscosity**
Class:	**III (Rules 8 and 14 of annex VIII)**	
GMDN designation:	**46059 - orthopaedic cement medicated**	
EMDN classification:	**P099001 - orthopaedic cements**	
Basic UDI-DI:	**376017704B01CS**	

Meet all the provisions of the
- **Regulation (EU) 2017/745**

Conformity assessment procedure
- **Annex IX, Chapters I, II and III**

EU Certificate
- **N° MDR 719475**

EU Technical Documentation Assessment Certificate
- **N° MDR 736239**

Notified Body
- **BSI Group The Netherlands B.V., n° 2797**

Say Building,
John M. Keynesplein 9,
1066 EP – Amsterdam
Netherlands

L'Union, (France) 13/12/2022

Digitally signed by Rusu Ghenadie
Date: 2023.10.19 11:22:58 EEST
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Stéphanie SALLES
Regulatory Affairs Manager