



EU DECLARATION OF CONFORMITY

We,

TEKNIMED SAS

8, rue du Corps Franc Pommiers

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, 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**

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

Notified Body

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

Say Building,

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