

EU declaration of conformity

I, the undersigned, Marlène Horgnies, the Person Responsible for the Regulatory Compliance of Medical Devices (PRRC), hereby declare that the medical device described below:

- complies with the relevant provisions, in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745, including an assessment of the technical documentation "DTCE_RD0208_017-m3_EN" drafted in compliance with Annexes II and III of the Regulation,
- complies with the applicable General Safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.

Product type		Disinfectant solution for invasive and non-invasive medical devices.	
Device name		High level disinfectant.	
Trade name		exeol GTA 2%	
Item code(s)	Unit packaging	EXS0092	Container of 5L
Basic UDI-DI		326824F3313-01WE	
Intended use		Ready-to-use glutaraldehyde-based solution for final disinfection by immersion of pre-cleaned semi-critical and critical reusable invasive and non-invasive heat-sensitive medical devices.	
Risk class	Rule (annex VIII)	Class IIb	Rule 16
Name of notified body	Identification No.	GMED - 1, Rue Gaston Boissier - 75015 PARIS	0459
Quality management system certified by the GMED in compliance with NF EN ISO 13485: 2016		Certificate No. 35009 rev.3 - Expiry date: 19 November 2024	
CE marking		EU Certificate No. 39301 rev.1 - Expiry date: 16 May 2028	

This EU declaration of conformity is issued under the sole responsibility of Sodel SAS, 190 rue René Barthélemy - 14100 Lisieux, registered with EUDAMED under SRN: **FR-MF-000000367** as manufacturer.

Lisieux, 2023-11-22

Marlène Horgnies

PRRC