

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 applicable General Safety and performance requirements set out in Annex I of Regulation (EU) 2017/745,
- has technical documentation "DTCE_RD0215_029_EN" drafted in compliance with Annexes II and III of the Regulation.


Product type		Cleaning solution for invasive and non-invasive medical devices.	
Device name		Multi-enzymatic detergent.	
Trade name		exeol clean 4E	
Item code(s)	Unit packaging	EXS0091 EXS0060 EXS0075	Container of 5L Dosing bottle of 1L x 20mL IWD container of 5L
Basic UDI-DI		326824F3350-01XS	
Intended use		Concentrated enzymatic solution to be diluted : <ul style="list-style-type: none"> • for cleaning by immersion of invasive and non-invasive reusable medical devices before sterilisation or final disinfection • for cleaning of surgical instruments and accessories in an IWD or tunnel washer before sterilisation. 	
Risk class	Rule (annex VIII)	Class I	Rule 1
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	

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, 2023-06-26

Marlène Horgnies

PRRC




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- has technical documentation "DTCE_RD0167_030_EN" drafted in compliance with Annexes II and III of the Regulation.

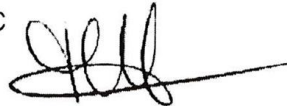
Product type		Cleaning solution for invasive and non-invasive medical devices.	
Device name		Non-foaming alkaline detergent.	
Trade name		exeol clean matic	
Item code(s)	Unit packaging	EXS0068 EXS0069	IWD container of 5L Container of 10L
Basic UDI-DI		326824F3159-01YA	
Intended use		Concentrated solution for cleaning of surgical instruments and accessories in an IWD or tunnel washer before sterilisation.	
Risk class	Rule (annex VIII)	Class I	Rule 1
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	

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- has technical documentation "DTCE_RD0168_032_EN" drafted in compliance with Annexes II and III of the Regulation.

Product type		Rinsing solution for invasive and non-invasive medical devices	
Device name		Drying activator rinsing liquid.	
Trade name		exeol rinse matic	
Item code(s)	Unit packaging	EXS0071 EXS0077	IWD container of 5L Container of 10L
Basic UDI-DI		326824F3292-01YJ	
Intended use		Concentrated solution for the final rinsing of surgical instruments and accessories in an IWD or tunnel washer before sterilisation.	
Risk class	Rule (annex VIII)	Class I	Rule 1
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	

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