# 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.

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| **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



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S.A.S au capital de 352 350€ - RCS Lisieux 627 150 105 00070 – TVA Intra. : FR12 627 150 105 – APE 2041Z – Code emballeur : 14366B