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SELF-DECLARATION OF CONFORMITY

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We declare that our **labels with Type 1 process indicator** are registered on the Ministry of Health's website with the MDR number 2322848 as class I medical devices and do not need a CE declaration due to the nature of the product.

Labels with steam indicator Basic UDI-DI 802256227NC
Labels with Eo indicator Basic UDI-DI 802256228NE
Labels with Vh2O2 indicator Basic UDI-DI 802256229NG

Relevant Harmonized Standards

EN ISO 13485:2016
EN ISO 9001:2015
EN ISO 14001:2015

Other Regulation, Legislation & Guidelines

This self-declaration of conformity is based on the Annex IV D. Lgs. 745/17.

Colleferro, 15/11/2023

A. Maurizio Gabrieli
Legal Representative