Via Zonta, 3 – 35010 – Limena (PD)
Tel.049768712- fax 049769497

Medical device
DECLARATION OF CONFORMITY

M0801.0

rev. of 30/11/2021

The Technical Director of the Company MONDIAL s.n.c. of Limena (Pd)

DECLARES
and
GUARANTEES

that the product thus identified

IGENAL N	FMXXXX	XXXXX	YYYY/MM
name	code	Batch	Expiry

- Is a medical device intended for

DISINFECT INVASIVE MEDICAL DEVICE

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meets the essential requirements
applicable as required by Annex I of Directive 93/42 EEC and subsequent amendments on medical devices

with definition of specific quality system requirements in the field of medical devices according to UNI CEI EN ISO 13485: 2016.
For this purpose it guarantees and declares under its own responsibility the following:

- that the indicated device is manufactured according to the provisions of the documentation prepared in accordance with Annex II of the aforementioned directive, within the complete quality assurance system approved and monitored by CERTIQUALITY via Gaetano Giardino, 4, 20123, Milan, Notified Body by the Italian Ministry of Health with number 0546 and represented by certificate no. 25296/1 with expiry 2024 and concerning the family of products: liquid and powder disinfectants for invasive and non-invasive medical devices manufactured in the operating unit of 35010 Limena PD Via Don Zonta, 3 in accordance with the provisions in force; furthermore, the device is to be considered compliant with all applicable technical standards listed in the technical file;

- that the device indicated is to be considered as belonging to **Class IIB**;

- that the indicated device is sold in **NON-STERILE** packaging**;**

- that the device has no measurement functions;

- does not include medicines or blood products;

- does not include tissues of animal origin or phthalates;

- that he undertakes to keep and make the product technical file available to the Competent Authority, for a period of at least ten years from the last date of manufacture of the product;

- that the indicated device is manufactured anda marketed with CE marking according to what is indicated in the product technical file;

The manufacturer also declares that it has set up and maintains a suitable system to guarantee post-sale surveillance as required by article 120 paragraph 3 of EU Regulation 745/2017.

Date: Sign