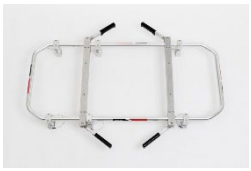
FERNO S.R.L. VAT NUMBER 01693660977 Capital € 53.712,00 Sole shareholder
Tel +39 051 6860028 - Fax +39 051 6861508 - Email info.it@ferno.com - Pec info-cert@pec.ferno.it
Via B. Zallone 26 – 40066 Pieve di Cento (BO) ITA www.ferno.it

# EU DECLARATION OF CONFORMITY

| MANUFACTURER | |
|---|---|
| **Name of Company and Address** | **EUDAMED SRN / Application ID** |
| **FERNO S.r.l**<br>Via B. Zallone n.26<br>40066 Pieve di Cento (BO) Italy<br>+39 (051) 6860028<br>www.ferno.it | **IT-MF-000031330** / APP000027477 |

| SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER | |
|---|---|
| **Name of Company and Address** | **Swiss Single Registration Number (CHRN)** |
| **FERNO S.r.l Pieve di Cento, succursale di Savosa**<br>Via Tesserete, 67<br>6942 Savosa, Switzerland<br>+41 (41) 259 60 00<br>www.ferno-schweiz.ch | CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE<br>CHRN-IM-20002288 - IMPORTER |

**The manufacturer declares under its own responsibility that the medical device(s):**

| PRODUCT IDENTIFICATION | | | |
|---|---|---|---|
| **Product Brand Name** | | **Photo** | |
| FERNO, ITC-HL (Heavy Load) | |   | |
| **EMDN** | | | |
| V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES | | | |
| **Intended Purpose** | | | |
| Interface for the transport of neonatal patients. | | | |
| **REF (Item / Catalog)** | **Item Description** | **GTIN (UDI-DI)** | **GMN (Basic UDI-DI)** |
| ITC-HL-GT5400 | INCUBATOR TRANSPORT INTERFACE DRG | 08051380871133 | 805138087Z1208040302ITC46 |
| ITC-HL | INCUBATOR TRANSPORT INTERFACE | 08051380871140 | 805138087Z1208040302ITC46 |
| ITC-HL-INX | INCUBATOR TRANSPORT INTERFACE FOR INX/ML MB | 08051380871157 | 805138087Z1208040302ITC46 |
| ITC-HL-BML | INCUBATOR TRANSPORT INTERFACE FOR MONDIAL | 08051380871164 | 805138087Z1208040302ITC46 |
| **RISK CLASS FOR MEDICAL DEVICES** | | | |
| **Device Classification** | **Common Specifications** | | |
| Class I Rule 1 | Not applicable | | |

**according to:**

| HARMONIZED AND NON-HARMONIZED STANDARDS | |
|---|---|
| **Item** | **Description** |
| EN 1789:2020 para(s). 4.4.11 and 5.3 | Medical vehicles and their equipment - Road ambulances |
| EN ISO 10993-1:2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018) |
| EN ISO 14971:2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN ISO 13485:2016+A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| EN ISO 9001:2015 | Quality management systems - Requirements (ISO 9001:2015) |

**complies with the essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.**

Pieve di Cento, July 27, 2023

Signature
*Enrico Carletti - Managing Director, PRRC*

*This document is compiled in accordance with Annex IV - EU declaration of conformity*

*FORM-021-02 2022-12-15 EN*