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, RESCUE KIT | |  | |
| **EMDN** | | | |
| V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES | | | |
| **Intended Purpose** | | | |
| The RESCUE KIT is designed for the transportation of patients during rescue operations. | | | |
| **REF (Item / Catalog)** | **Item Description** | **GTIN (UDI-DI)** | **GMN (Basic UDI-DI)** |
| 21-00027 | FLYING III-Y AND B-LOCK | 08051380871362 | 805138087V080504TELI3D |

| RISK CLASS FOR MEDICAL DEVICES | |
|---|---|
| **Device Classification** | **Common Specifications** |
| Class I Rule 1 | Not applicable |

**according to:**

| HARMONIZED AND NON-HARMONIZED STANDARDS | |
|---|---|
| **Item** | **Description** |
| EASA CS-27.865(a) and CS-29.865(a) EASA CM-CS-005 | European Union Aviation Safety Agency – “External loads” and “Helicopter External Loads Personnel Carrying Device System" issued 08 December 2014 |
| EN 1865-1:2010+A1:2015 | Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment. |
| 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 62366-1:2015+A1:2020 | Medical devices - Part 1: Application of usability engineering to medical devices |
| 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 general safety and performance requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.**

Pieve di Cento, March 23, 2024

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*