






EU DECLARATION OF CONFORMITY

| MANUFACTURER | |
|--|---|
| Name of Company and Address | EUDAMED SRN / Application ID |
|  FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  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 Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00  www.ferno-schweiz.ch | CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER |

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

| PRODUCT IDENTIFICATION | | | |
|--|---|----------------|----------------------|
| Product Brand Name | Photo | | |
| FERNO, FERNO, 5126-EL-IT / 5226-EL-IT / CUSTOM-M-IT series (Easy Load) |  | | |
| EMDN | | | |
| V080502 - SELF-LOADING STRETCHERS | | | |
| Intended Purpose | | | |
| 5126-EL-IT/5226-EL-IT/ CUSTOM-M-IT self-loading multi-level stretcher is designed to be used with the Ferno SLAM locking system to transport patients in safety and in comfort in an ambulance. Maximum load 250 kg. | | | |
| REF (Item / Catalog) | Item Description | GTIN (UDI-DI) | GMN (Basic UDI-DI) |
| 5126-EL-IT | SELF-LOADING MULTI LEVEL STRETCHER | 08051380870433 | 805138087V080501024M |
| 5226-EL-IT | SELF-LOADING MULTI LEVEL STRETCHER | 08051380870532 | 805138087V080501024M |
| CUSTOM-M-IT | SELF-LOADING MULTI LEVEL STRETCHER | 08051380870549 | 805138087V080501024M |
| 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 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 essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.

Pieve di Cento, March 13, 2024

Signature
Enrico Carletti - Managing Director, PRRC

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

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