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 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, 5126-EL-IT/5226-EL-IT/ CUSTOM-M-IT/ CORTEX (Easy Load)			
EMDN			
V08050102 - SELF-LOADING STRETCHERS			
Intended Purpose			
5126-EL-IT/5226-EL-IT/ CUSTOM-M-IT/ CORTEX 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
21-00059	CORTEX	08051380871843	805138087V080501024M
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 general safety and performance requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.

Pieve di Cento, January 22, 2025

Signature

Katarzyna Zofia Chrusciel - ***Manager, EU PRRC***

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

FORM-021-02 2022-12-15 EN