






## EU DECLARATION OF CONFORMITY

MANUFACTURER	
Name of Company and Address	EUDAMED SRN / Application ID
 <b>FERNO S.r.l</b> Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  <a href="http://www.ferno.it">www.ferno.it</a>	<b>IT-MF-000031330 / APP000027477</b>
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
Name of Company and Address	Swiss Single Registration Number (CHRN)
 <b>FERNO S.r.l Pieve di Cento, succursale di Savosa</b> Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00  <a href="http://www.ferno-schweiz.ch">www.ferno-schweiz.ch</a>	<b>CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE</b> <b>CHRN-IM-20002288 - IMPORTER</b>

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

PRODUCT IDENTIFICATION			
Product Brand Name		Photo	
FERNO, 26-B series (Bariatrics)			
EMDN			
V08050102 - SELF-LOADING STRETCHERS			
Intended Purpose			
26-B self-loading stretcher is designed to be used with the FERNO SLAM locking system to transport very large patients (bariatrics) in safety and in comfort in an ambulance. Load limit 280 kg.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
26-B-R	SELF-LOADING MULTI LEVEL STRETCHER	08051380870440	805138087V080501024M
26-B-R-IT	SELF-LOADING MULTI LEVEL STRETCHER	08051380870860	805138087V080501024M
Device Classification		Common Specifications	
Class I Rule 1		Not applicable	

**according to:**

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, March 13, 2024

  
 Signature  
**Enrico Carletti** - Managing Director, PRR

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

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