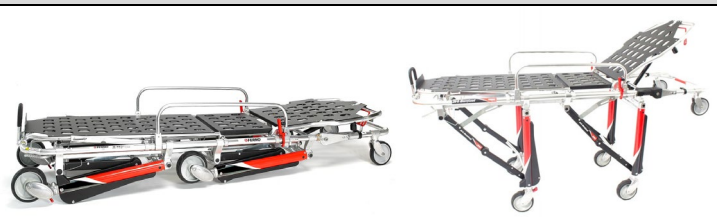
FERNO S.R.L. VAT NUMBER 01693660977 CAPITAL € 53.712,00 SOLE SHAREHOLDER
Tel +39 051 6860028 - Fax +39 051 6861508 - Email info@ferno.it Pec info-cert@ferno.it
Via B. Zallone 26 – 40066 Pieve di Cento (BO) ITA www.ferno.it

EU DECLARATION OF CONFORMITY

MANUFACTURER		
Name of Company	**Address**	**SRN / Application ID**
FERNO S.r.l CE	Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy (+39) 0516860028 www.ferno.it	Not yet available / APP000027477
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER		
Name of Company	**Address**	**Swiss Single Registration Number (CHRN)**
FERNO S.r.l Pieve di Cento, succursale di Savosa CH REP	Via Tesserete, 67 6942 Savosa Switzerland 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, 26 series			
EMDN			
V08050102 - SELF-LOADING STRETCHERS			
Intended Purpose			
26-B self-loading stretcher is designed to be used with the FERNO SLAM-26 locking system to transport very large patients (bariatrics) in safety and in comfort in an ambulance.			
REF (Item / Catalogue)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
26-B-R	26-B high capacity roll-in cot, load limit 280 kg	08051380870440	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 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 7th 2022

Signature
Enrico Carletti - Managing Director

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

Rev.02 2022-07-01 EN