FERNO S.R.L. n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale
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EU DECLARATION OF CONFORMITY

MANUFACTURER		
Name of Company	**Address**	**SRN / Application ID**
FERNO S.r.l	Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy	Not yet available / APP000027477

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

PRODUCT IDENTIFICATION			
Product Brand Name		**Photo**	
5126-EL/5226-EL Series			
EMDN			
V08050102 - SELF-LOADING STRETCHERS			
Intended Purpose			
5126-EL/5226-EL 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.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
5126-EL	Self-loading Multi Level Stretcher	08051380870334	805138087V080501024M
5226-EL	Self-loading Multi Level Stretcher	08051380870341	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 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
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, April 13th 2022

Signature
Enrico Carletti - Managing Director

This document is compiled in accordance with *Annex IV - EU declaration of conformity* Rev.01 2021-05-26 ENG