

EU DECLARATION OF CONFORMITY

MANUFACTURER	
Name of Company and Address	EUDAMED SRN / Application ID
 www.ferno.it FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028 	IT-MF-000031330 / APP000027477
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
Name of Company and Address	Swiss Single Registration Number (CHRN)
  www.ferno-schweiz.ch FERNO S.r.l Pieve di Cento, succursale di Savosa Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00	CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER
UK RESPONSIBLE PERSON AND IMPORTER	
Name of Company and Address	MHRA Reference Number
 www.ferno.co.uk FERNO (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999	12246

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

PRODUCT IDENTIFICATION			
Product Brand Name	Photo		
FERNO, Stretcher Restraints Model 50MM in Polyester (PL)			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
Ferno restraints may be used with Wheeled/Hand Carried Stretchers and are designed to secure a patient on the stretcher while being transported.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
313915	4-point restraints	08051380870358	805138087V0880PL50HC
314122	Belt with metal carabiner	08051380870365	805138087V0880PL50HC
770-E	Patient belt system 770-E	08051380870372	805138087V0880PL50HC
430-2-N	Two-piece quick release black belt	08051380870389	805138087V0880PL50HC
430-1-N	Black quick release belt	08051380870396	805138087V0880PL50HC
430-PA-1-N	Amagnetic belt with plastic buckle black	08051380870402	805138087V0880PL50HC
430-PA-2-N	Two-piece amagnetic belt with plastic buckle black	08051380870419	805138087V0880PL50HC
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 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 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
SKIN SENSITISATION AND IRRITATION	Alternative method for quantification of nitric oxide (NO) and interleukin-6 (IL-6), as predictive markers of skin sensitisation or irritation based on human primary fibroblasts.
EN ISO 13934-1:2013	Textiles - Tensile properties of fabrics - Part 1: Determination of maximum force and elongation at maximum force using the strip method (ISO 13934-1:2013)
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, March 7, 2023

Signature

Enrico Carletti - Managing Director, PRRC

