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/UK 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

UK RESPONSIBLE PERSON AND IMPORTER	
Name of Company and Address	**MHRA Reference Number**
FERNO (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999 www.ferno.co.uk	12246

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

PRODUCT IDENTIFICATION			
Product Brand Name		**Photo**	
FERNO, XT ACCESSORIES			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
The sets are accessories to the XT extricator to transform it into an XT Floating, XT PRO or XT PRO Military.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
KIT FLOATING	KIT FLOATING FOR XT	08051380871386	805138087V0880KITRESTLT
KIT PRO	KIT PRO FOR XT PRO	08051380871379	805138087V0880KITRESTLT
KIT PRO M	KIT PRO M FOR XT PRO MILITARY	08051380871744	805138087V0880KITRESTLT

Device Classification	Common Specifications
Class I Rule 1	Not applicable

according to:

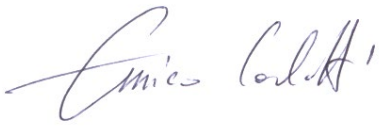
HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	**Description**
EN 1865-1:2010+A1:2015	Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment.
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within 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 and with the Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791), 2020 (SI 1478) and 2023 (SI 627).

Pieve di Cento, March 13, 2024

Signature
Enrico Carletti - Managing Director, PRRC



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

FORM-021-02 2022-12-15 EN