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
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EU 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

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

PRODUCT IDENTIFICATION			
Product Brand Name		**Photo**	
FERNO, MONORUDDER			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
Motorized evacuation system is a medical device made for transporting a patient in sitting position, on stairs and on flat surfaces.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
21-0090-001	MOTORIZED SYSTEM (x Utila, Dlouhy e Venice)	08051380871201	805138087V0880MORBK
25-1100-048	FASTENER MONOCLACK FOR MONORUDDER	08051380871218	805138087V0880MORBK

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class I Rule 1 (25-1100-048) and Rule 13 (21-0090-001)	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 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, February 27, 2024

Signature
Enrico Carletti - Managing Director, PRRC

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

FORM-021-03 2023-04-20 EN