






EU DECLARATION OF CONFORMITY

MANUFACTURER	
Name of Company and Address  FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  www.ferno.it	EUDAMED SRN / Application ID IT-MF-000031330 / APP000027477
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
Name of Company and Address   www.ferno-schweiz.ch	Swiss Single Registration Number (CHRN) CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER

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

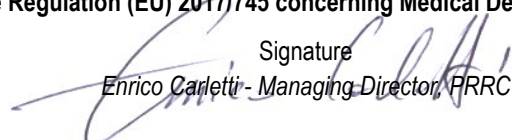
PRODUCT IDENTIFICATION			
Product Brand Name		Photo	
FERNO, RESCUE KIT			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
The RESCUE KIT is designed for the transportation of patients during rescue operations.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
21-00027	FLYING III-Y AND B-LOCK	08051380871362	805138087V080504TELI3D
RISK CLASS FOR MEDICAL DEVICES			
Device Classification		Common Specifications	
Class I Rule 1		Not applicable	

according to:

HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	Description
EASA CS-27.865(a) and CS-29.865(a) EASA CM-CS-005	European Union Aviation Safety Agency – “External loads” and “Helicopter External Loads Personnel Carrying Device System” issued 08 December 2014
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 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.

Pieve di Cento, March 23, 2024


 Signature
Enrico Carletti - Managing Director, FRRC