FERNO S.R.L. VAT NUMBER 01693660977 Capital € 53.712,00 Sole shareholder
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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, SAERBAG			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
The rescue bag is designed for the transportation of patients during rescue operations.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
SAERBAG III-G	RESCUE BAG MILITARY	08051380871102	805138087V080504TELI3D
SAERBAG III-R	RESCUE BAG, RED	08051380871119	805138087V080504TELI3D
SAERBAG III-Y	RESCUE BAG, YELLOW	08051380871126	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 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, PRRC

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

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