






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   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	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, 40-E and 42-E serie			
EMDN			
V080502 - PATIENT TRANSFER CHAIRS			
Intended Purpose			
The sedan chair is a medical device. It is used to handle and carry a non-critical, non-traumatic patient in a sitting position to the road ambulance and to be used to transport a patient within the ambulance. It is easy to use and thanks to the two or four wheels, it is easy to maneuver in limited spaces and transport on most surfaces.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
42-E	SEDAN CHAIR 4 WHEELS ABS BLACK	08051380871577	805138087V08050242EFC
40-E	SEDAN CHAIR 2 WHEELS ABS BLACK	08051380871683	805138087V08050242EFC
Device Classification			
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 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 essential 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

