





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, Stair Chair Family			
EMDN			
V080502 - PATIENT TRANSFER CHAIRS (21-00054, 21-00037) V0880 - MEDICAL SUPPORT EQUIPMENT – ACCESSORIES (25-00112, T-59T IN EZG-PWR V5)			
Intended Purpose			
An emergency patient handling medical device designed and intended for use in transporting a patient in a seated position. For professional use by a minimum of two trained operators.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
21-00054	59T CHAIR RED WITH POWERTRAXX	08051380871416	805138087V08050259TH4
25-00112	KIT 59T VENICE LOCK	08051380871539	805138087V0880VLSCR
T-59T IN EZG-PWR V5	FROM 59T TO EZGLIDE POWER V5	08051380871713	805138087V0880VLSCR
21-00037	59T RED CHAIR WITH TRAXX MECHANICAL	08051380871720	805138087V08050259TH4
Device Classification		Common Specifications	
Class I Rule 1 (25-00112, 21-00037) and Rule 13 (21-00054, T-59T IN EZG-PWR V5)		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 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

