

## EU/UK DECLARATION OF CONFORMITY

MANUFACTURER	
<b>Name of Company and Address</b>  <b>FERNO S.r.l</b> Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028 <a href="http://www.ferno.it">www.ferno.it</a>	<b>EUDAMED SRN / Application ID</b> IT-MF-000031330 / APP000027477 
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
<b>Name of Company and Address</b>   <b>FERNO S.r.l Pieve di Cento, succursale di Savosa</b> Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00 <a href="http://www.ferno-schweiz.ch">www.ferno-schweiz.ch</a>	<b>Swiss Single Registration Number (CHRN)</b> CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER
UK RESPONSIBLE PERSON AND IMPORTER	
<b>Name of Company and Address</b>  <b>FERNO (UK) Ltd,</b> Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999 <a href="http://www.ferno.co.uk">www.ferno.co.uk</a>	<b>MHRA Reference Number</b> 12246

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

PRODUCT IDENTIFICATION			
<b>Product Brand Name</b>		<b>Photo</b>	
FERNO, FERNO, Track System			
<b>EMDN</b>			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
<b>Intended Purpose</b>			
Manual Track is an accessory for the FERNO Venice Base chair. It allows you to transform the SEDAN chair into an evacuation chair. Motorized Track is an accessory for the FERNO Venice Base and Venice Plus chair. It allows you to transform the Venice Base and Venice Plus models into a Venice Power motorized chair.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
21-00025	KIT TRAXX MECHANICAL FOR BASIC VENICE	8051380871294	805138087V0880VLSCR
21-00023	MOTORISATION KIT FOR THE BASIC VENICE	8051380871706	805138087V0880VLSCR
21-00024	MOTORISATION KIT FOR THE VENICE PLUS	8051380871737	805138087V0880VLSCR
RISK CLASS FOR MEDICAL DEVICES			
<b>Device Classification</b>		<b>Common Specifications</b>	
Class I Rule 1 (21-00025) and Rule 13 (21-00023, 21-00024)		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 and with the Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791), 2020 (SI 1478) and 2023 (SI 627).

Pieve di Cento, February 27, 2024

Signature

Enrico Carletti - Managing Director, PRRC

