FERNO S.R.L. VAT NUMBER 01693660977 Capital € 53.712,00 Sole shareholder
Tel +39 051 6860028 - Fax +39 051 6861508 - Email info.it@ferno.com - Pec info-cert@pec.ferno.it
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EU/UK 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
UK RESPONSIBLE PERSON AND IMPORTER	
Name of Company and Address	**MHRA Reference Number**
FERNO (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999 www.ferno.co.uk	12246

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

PRODUCT IDENTIFICATION			
Product Brand Name		**Photo**	
FERNO, VENICE series			
EMDN			
V080502 - PATIENT TRANSFER CHAIRS			
Intended Purpose			
Model FERNO VENICE is evacuation chair for transporting a seated patient, on stairs and flat surfaces. The VENICE series based on a large and robust chair frame includes a wide range of chairs configurable with a series of accessories and compatible with manual (VENICE PLUS) and motorized (VENICE POWER) track system.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
21-0101-001	VENICE PICKUP CHAIR	08051380870709	805138087V080502VENICEE4
21-0083-001-UKBLK	VENICE POWER UK BLACK CHAIR	08051380870716	805138087V080502PWRPR
21-0083-001-PRO	VENICE POWER PRO LIGHT CHAIR	08051380870723	805138087V080502PWRPR
21-0083-001-BLK	VENICE POWER BLACK CHAIR WITH FOOTREST	08051380870730	805138087V080502PWRPR
21-0083-001-UK	VENICE POWER UK CHAIR	08051380870075	805138087V080502PWRPR
21-0083-001	VENICE POWER CHAIR WITH FOOTREST	08051380871492	805138087V080502PWRPR
21-0082-001-UKBLK	VENICE PLUS UK BLACK CHAIR	08051380870747	805138087V080502VENICEE4
21-0082-001-UK	VENICE PLUS UK CHAIR	08051380870754	805138087V080502VENICEE4
21-0082-001-IT	VENICE PLUS CHAIR	08051380870761	805138087V080502VENICEE4
21-0082-001-BLK	VENICE PLUS BLACK CHAIR WITH FOOTREST	08051380870778	805138087V080502VENICEE4
21-0082-001	VENICE PLUS CHAIR BASIC	08051380871645	805138087V080502VENICEE4
21-0081-001-BLK	VENICE BASE BLACK CHAIR WITH FOOTREST	08051380870785	805138087V080502VENICEE4
21-0081-001	VENICE BASE CHAIR WITH FOOTREST	08051380871485	805138087V080502VENICEE4

21-00060	VENICE UK CHAIR V6	08051380871850	805138087V080502PWRPR
21-00061	VENICE POWER CHAIR V6	08051380871867	805138087V080502PWRPR

Device Classification	Common Specifications
Class I Rule 1 (Manual Track) and Rule 13 (Powertraxx)	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 60601-1-2:2015 /A1:2021 AAMI ANSI IEC 60601-1-2:2014 (ONLY VENICE POWER)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014 /A1:2020)
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 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, July 9, 2025

Signature
Katarzyna Zofia Chrusciel - ***Manager, EU PRRC***
Katarzyna Chrusciel