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
Via B. Zallone 26 – 40066 Pieve di Cento (BO) ITA www.ferno.it

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, HEAD IMMOBILIZER AND ACCESSORIES		 	
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
Head immobilizer and accessories are the medical devices that ensure maximum immobilization of the neck during transport. Compatible with FERNO stretchers and spinal boards.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
21-00022	B-LOCK HEAD IMMOBILIZER	08051380870068	805138087V0880HIMMK2
25-0059-002	H-BELT	08051380871546	805138087V0880HIMMK2
25-0601-002	CHIN STRAP FOR THE QHI	08051380871553	805138087V0880HIMMK2

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class I Rule 1	Not applicable

according to:

HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	**Description**
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)

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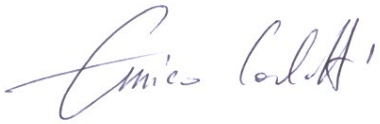
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability 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, March 22, 2024

Signature
Enrico Carletti - Managing Director, PRRC



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

FORM-021-03 2023-04-20 EN