FERNO S.R.L. VAT NUMBER 01693660977 CAPITAL € 53.712,00 SOLE SHAREHOLDER
Tel +39 051 6860028 - Fax +39 051 6861508 - Email info@ferno.it Pec info-cert@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	1270

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

PRODUCT IDENTIFICATION	
Product Brand Name	**Photo**
FERNO, TIROL KIT	 **Special Forces Equipment NATO Suppliers List NCAGE No. AL707** https://eportal.nspa.nato.int/Codification/CageTool/home
EMDN	
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES	
NATO NUMBER (NSN)	
4220150208384	
Intended Purpose	
The Tirol Kit recovery system is an accessory of the Titan basket stretchers developed to facilitate rescue operations in arduous environments, making transportation safer. The Tirol Kit is available in different configurations.	

REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
21-0120-023	TIROL KIT FOR TITAN	08051380870099	805138087V0880TKTCE
21-00055	TIROL KIT WITH WHEEL XXL AND BRAKE	08051380871065	805138087V0880TKTCE
21-00056	TIROL KIT XTREME WITH WHEEL XXL	08051380871614	805138087V0880TKTCE
25-00082	KIT PLATES HANDLE TITAN TAPERED	08051380871621	805138087V0880TKTCE
25-00099	KIT PLATES HANDLE TITAN REGULAR	08051380871638	805138087V0880TKTCE

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

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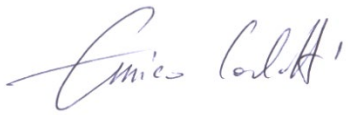
according to:

HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	**Description**
EASA CS-27.865(a) and CS-29.865(a) EASA CM-CS-005	European Union Aviation Safety Agency – "External loads" and "Helicopter External Loads Personnel Carrying Device System" issued 08 December 2014
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	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 and with the Medical Devices Regulation 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 02, 2024

Signature
Enrico Carletti - Managing Director



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

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