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 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, XT PRO Serie			
EMDN			
V08050103 - EMERGENCY AND TRAUMATOLOGY STRETCHERS			
NATO NUMBER (NSN)			
6530150200591			
Intended Purpose			
XT PRO is medical device designed for spinal immobilization and extrication during vertical rescue in isolated environments.		**Special Forces Equipment NATO Suppliers List NCAGE No. AL707** https://eportal.nspa.nato.int/Codification/CageTool/home	
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
XT PRO	KIT XT PRO WITH HUMAN LIFT BRIDLES	08051380870082	805138087V08050103XTRR

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 1498	Personal fall protection equipment - Rescue loops
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 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
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.

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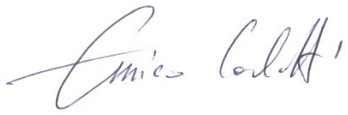
LOOPS (TRUCK LOOP 120 cm BLACK - **2034120B**) – Notified Body 0123 TÜV SÜD Product Service GmbH (module D)	
Regulation (EU) 2016/425	European Regulation on personal protective equipment (PPE)
ANSI/ASSE Z359.1	The Fall Protection Code (USA) - Anchorage connector 1 person max 5000 lbs - **22.2 kN**
EN 354: 2010 EN 795/B:2012	Personal fall protection equipment – Lanyards - Breaking load **45 kN** Personal fall protection equipment - Anchor devices EU Type Examination (module B) APAVE SUDEUROPE SAS Notified Body 0082
EAC TP TC 019/2011	Eurasian Conformity mark (EAC, Russia-Belarus-Kazakhstan-Armenia-Kyrgyzstan) is a certification mark to indicate products that conform to all technical regulations of the Eurasian Customs Union - Breaking load **45 kN**
CARABINER (3C4650A) – Notified Body 0333 AFNOR Certification (module D)	
Regulation (EU) 2016/425	European Regulation on personal protective equipment (PPE)
EN 362:2004	Personal protective equipment against falls from a height – Connectors EU Type Examination (module B) DOLOMITICERT s.c.ar.l. Notified Body 2008

Pieve di Cento, December 15th 2022

Signature
Enrico Carletti - Managing Director



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

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