


EU DECLARATION OF CONFORMITY

MANUFACTURER		
Name of Company	Address	SRN / Application ID
FERNO S.r.l	Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy	Not yet available / APP000027477

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.			
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 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.

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	Personal fall protection equipment – Lanyards - Breaking load 45 kN
EN 795/B:2012	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, May 26th 2021

Signature
 Enrico Carletti - Managing Director

