

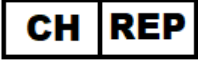



## EU DECLARATION OF CONFORMITY

MANUFACTURER	
<b>Name of Company and Address</b>  <b>FERNO S.r.l</b> Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  <a href="http://www.ferno.it">www.ferno.it</a>	<b>EUDAMED SRN / Application ID</b> IT-MF-000031330 / APP000027477
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
<b>Name of Company and Address</b>  <b>FERNO S.r.l Pieve di Cento, succursale di Savosa</b> Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00 <a href="http://www.ferno-schweiz.ch">www.ferno-schweiz.ch</a>	<b>Swiss Single Registration Number (CHRN)</b> CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER

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

PRODUCT IDENTIFICATION			
<b>Product Brand Name</b>	<b>Photo</b>		
FERNO, XT Serie	 <b>Special Forces Equipment NATO Suppliers List NCAGE No. AL707</b> <a href="https://eportal.nspa.nato.int/Codification/CageTool/home">https://eportal.nspa.nato.int/Codification/CageTool/home</a>		
<b>EMDN</b>			
V08050103 - EMERGENCY AND TRAUMATOLOGY STRETCHERS			
<b>NUMERO NATO (NSN)</b>			
6530150200592			
<b>Intended Purpose</b>	XT FLOATING is a kit designed for the immobilization and maintenance of the head-neck-trunk axis of patients traumatized (and not) during the rescue procedures in water.		
<b>REF (Item / Catalog)</b>	<b>Item Description</b>	<b>GTIN (UDI-DI)</b>	<b>GMN (Basic UDI-DI)</b>
XT FLOATING	KIT XT FLOATING, <b>maximum load 160 kg</b>	08051380870488	805138087V08050103XTRR
RISK CLASS FOR MEDICAL DEVICES			
<b>Device Classification</b>	<b>Common Specifications</b>		
Class I Rule 1	Not applicable		

**according to:**

HARMONIZED AND NON-HARMONIZED STANDARDS	
<b>Item</b>	<b>Description</b>
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 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.**

 Pieve di Cento, December 15<sup>th</sup> 2022

Signature  
 Enrico Carletti - Managing Director  
