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

DICHIARAZIONE DI CONFORMITÀ UE

MANUFACTURER	
Name of Company and Address	**SRN / Application ID**
FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy (+39) 0516860028 www.ferno.it	Not yet available / 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 www.ferno-schweiz.ch	CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER

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

PRODUCT IDENTIFICATION			
Product Brand Name		**Photo**	
FERNO, XT Serie			
EMDN			
V08050103 - EMERGENCY AND TRAUMATOLOGY STRETCHERS			
NUMERO NATO (NSN)			
6530150200592			
Intended Purpose			
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.		**Fornitori Forze Speciali Attrezzatura NATO Lista NCAGE No. AL707** https://eportal.nspa.nato.int/Codification/CageTool/home	
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
XT FLOATING	KIT XT FLOATING, **maximum load 160 kg**	08051380870488	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 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, May 26th 2021

Signature
Enrico Carletti - Managing Director

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

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