FERNO S.R.L. *n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale*

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***

DECLARATION OF CONFORMITY
Regulation (EU) 2017/745

***Manufacturer*:**	FERNO S.r.l.
***Manufacturer's address*:**	Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy
Single Registration Number: ***(Art.31(2))***	*(available when the managing system will be implemented by the European Commission)*

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

Product code	Name of Device	Class (Annex VIII)
KIT XT PLUS-B	EXTRICATION DEVICE XT "B" COMPLETE	I
KIT XT COMPLETE-B	COMPLETE XT: BOARD, BAG, RESTRAINTS, QHI-B	I
XT PRO	KIT XT PRO WITH HUMAN LIFT BRIDLES	I
XT FLOATING	XT FLOATING EXTRICATION DEVICE	I

Annex applied for the CE marking:	Annex II and Annex III
Basic UDI-DI	805138087XT003BRD0024N
Intended use:	Craniocaudal immobilization and extrication device

In accordance with the provisions of harmonized and non-harmonized standards:

(only for device XT PRO)
EN 1498:2006 Class A - Personal fall protection equipment — Rescue loops
EASA Regulatory requirement(s) CS-27.865(a) and CS-29.865(a) "*External loads*" – and in accordance to the EASA CM-CS-005 Issue 01 - "*Helicopter External Loads Personnel Carrying Device System*"

complies with the essential requirements listed in Annex I of the European Regulation 2017/745 concerning Medical Devices

Ferno maintains a Quality Management System that fulfills the requirements of ISO 13485:2016. Copies of Ferno's ISO 13485:2016 certificate issued by DNV is available upon request.

FERNO S.R.L. *n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale*

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***

Pieve di Cento, May 28Th 2021

Signature
Enrico Carletti - Managing Director

This document is compiled in accordance with *Annex IV - EU declaration of conformity* V: 2021.04_ENG