



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: (available when the managing system will be implemented by the European Commission)
(Art.31(2))

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

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Pieve di Cento, May 28th 2021

Signature

Enrico Carletti - Managing Director

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

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