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)
ITC-HL	ITC Heavy Load – Incubator Transport Interface	I
ITC-HL-INX	ITC Heavy Load – Incubator Transport Interface	I
ITC-HL-BML	ITC Heavy Load – Incubator Transport Interface	I

Annex applied for the CE marking: Annex II and Annex III

Basic UDI-DI 805138087ITCHL008UT

Intended use: Interface for the transport of neonatal patients

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

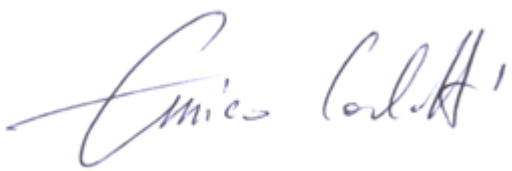
EN 1789:2007 + A2:2014 Medical vehicles and their equipment – Road ambulances

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.

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