

**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
(Art.31(2)) (by the European Commission)

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

Product code	Name of Device	Class (Annex VIII)
365-E	HEAD IMMOBLIZER 365-E	I

Annex applied for the CE marking: Annex II and Annex III
Basic UDI-DI 805138087IMBZ007F8
Intended use: Head/neck immobilizer for patient transportation on a stretcher

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 17th 2021

Signature
Enrico Carletti - Managing Director