



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

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

Product code	Name of Device	Class (Annex VIII)
SAERBAG III-Y	SAERBAG 3 - Yellow	I
SAERBAG III-R	SAERBAG 3 - Red	I

Annex applied for the CE marking: Annex II and Annex III
Basic UDI-DI 805138087SRB005YG5
Intended use: Device for the recovery and transport of an injured patient in a hostile environment

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

UNI EN 1865-1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment.
EASA Certification Memorandum No: CM-CS-005 Issue 01 issued 08 December 2014 Regulatory requirements: CS 27/29.865.

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 13th 2021

Signature
Enrico Carletti - Managing Director