



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)
0108002	SCOOP 65 EXL – Yellow, (PIN)	I
0107956	SCOOP 65 EXL – Yellow, (no PIN)	I
0108038	SCOOP 65 EXL – Red (PIN)	I
0108039	SCOOP 65 EXL – Red (no PIN)	I
0107996	SCOOP 65 EXL – Grey (no PIN)	I
0108008	SCOOP 65 EXL – Green (PIN)	I
0107999	SCOOP 65 EXL – Green (no PIN)	I

Annex applied for the CE marking: Annex II and Annex III
Basic UDI-DI 805138087SCP65EXL000G8
Intended use: Patient Transport

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.

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

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