



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

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

Product code	Name of Device	Class (Annex VIII)
0313915	4-point restraints	I
430-2-N	Two-piece quick release black belt	I
430-1-N	Black quick release belt	I
430-PA-1-N	Amagnetic belt with plastic buckle black	I
430-PA-2-N	Two-piece amagnetic belt with plastic buckle black	I
0314122	Belt with metal carabiner	I
770-E	Patient belt system 770-E	I

**Annex applied for the CE marking:** Annex II and Annex III  
**Basic UDI-DI** 805138087RST009F4  
**Intended use:** Patient restraint device for transportation on a cot

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

ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity  
UNI EN ISO 13934-1:2013 - Textiles - Tensile properties of fabrics - Part 1: Determination of maximum force and elongation at maximum force using the strip method

**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

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Pieve di Cento, May 28<sup>th</sup> 2021

Signature  
Enrico Carletti - Managing Director

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

V: 2021.04\_ENG