



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)
21-0081-001	Venice	I
21-0082-001-IT	Venice Plus	I
21-0083-001	Venice Power	I
21-0083-001-UK	Venice Power UK	I
21-0083-001-PRO	Venice Power PRO Light	I

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

Basic UDI-DI 805138087VNC00CHR001

Intended use: Evacuation chair for transporting a seated patient

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

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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