



EC Declaration of Conformity

REGULATION (EU) 2017/745

Manufacturer: Ferno Australia Pty Ltd
Manufacturer's Address: 11 Johnstone Road, Brendale, Queensland 4500, Australia
Unique Registration Number (Art.31(2)): Available when the managing system will be implemented by the European Commission
EU Authorised Representative: Ferno S.r.l., Via B. Zallone 26, 40066, Pieve di Cento (BO), Italy

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

Name of Device(s): PacRac+ Equipment Platform
Product(s) Code: FWEPR+
FWEPR+IT
FWEPR+PX1
Class of device(s) (Annex VIII): 1
Annex applied for the CE Marking: Annex II and Annex III
Intended Use: The PacRac+ Equipment Platform is an accessory that mounts to an ambulance cot. The PacRac+ is designed to secure medical instruments.
Base UDI-DI: (Art.29(1)): (available when the managing system will be implemented by the European Commission)

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

EN 1789 – Medical Vehicles and their equipment – Road Ambulances

Complies with the essential requirements listed in Annex I of the European Regulation 2017/745 concerning Medical Devices.

Ferno Australia Pty Ltd maintains a Quality Management System that fulfills the requirements of ISO 9001:2015. Copies of Ferno Australia's ISO 9001:2015 certificate issued by Compliance Australia Certification Services is available upon request.

A handwritten signature in blue ink, appearing to read 'Scott West'.

Scott West – Managing Director

Brendale, Queensland, Australia
03 July 2020

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