



DECLARATION OF CONFORMITY
Regulation (EU) 2017/745

Manufacturer: Ferno Australia Pty Ltd
Manufacturer's address: 11 Johnstone Road, Brendale
Queensland 4500
Australia
EU Representative: FERNO S.r.l., Via B. Zallone n.26- 40066 Pieve di Cento (BO) – Italy
CE
UK Representative: Ferno (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton,
West Yorkshire, BD19 4TZ – United Kingdom
**UK
CA**

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

Name of device(s): PACRAC+
Product(s) Code: FWEPR+IT
FWEPR+PX1
Class of device(s): I
(Annex VIII)
Annex applied for the CE marking: Annex II and Annex III
Intended use: The PacRac+ Instrument Platform is an accessory that mounts to
an ambulance cot. The PacRac+ is designed to secure medical
instruments.
Base UDI-DI: 93484980FWEPR+ZE
(Art.29(1))

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 is an ISO9001:2015 certified company.

Robert Hall
National Quality and Compliance Manager

25/05/2021

This document is compiled in accordance with *Annex IV - EU declaration of conformity*
V: 2021_03_ENG