Declaration of Conformity

For PACIFIC SHOWER BATHING TROLLEY

European Communities Council Regulation 2017/745 Medical Devices, 2017/2102 Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment as transposed into European national law by the member states, and UK MDR 2002.

The undersigned declares that the devices described in this document fulfil the requirements specified by European Council and UK provisions that apply to them and the CE Mark and UKCA may be affixed. By drawing up this EU Declaration of Conformity the manufacturer assumes responsibility for compliance with the above regulations and all other EU legislation.

General Product Name:	Pacific Shower Bathing Trolley (PSBT)
Legal Manufacturer: (Name on Label)	HOWARD WRIGHT LIMITED 17 PARAITE ROAD NEW PLYMOUTH 4312 NEW ZEALAND SRN: To Be Announced
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Basic UDI-DI	934409000PSBTET
Intended Use:	The PSBT is mainly used in assisting the prevention, treatment and alleviation of disease, or compensation for an injury or disability. The PSBT is designed to be used by trained health professionals and lay persons where the PSBT is located in a home environment. The PSBT is used generally within a hospital ward, nursing home or any other medical institution as a means of bathing and showering of patients and transporting patients from one area to another for the purpose of bathing or showering. In the home healthcare environment, the PSBT is generally stationary. The PSBT is intended to support one patient up to a weight not exceeding 200kg (including the mass of water and accessories).
Medical Device Regulation Classification:	Annex VIII, Active Devices 6.5 - Rule 13
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. SRN: MT-AR-000000234
UK Responsible Person:	Advena Ltd. Pure Offices, Plato Close, Warwick, CV34 6WE, United Kingdom.

HOWARD WRIGHT
Medical Beds & Stretchers

Version: 3

EU Declaration of Conformity

UK Declaration of Conformity

Date: 2021-06-09

Medical Device Directive Conformity Assessment Route:	Self-certification by Medical Device Regulation 2017/745 Annex IV and Article 19; EC Declaration of Conformity, and Article 10, and Article 31, and Article 52.
Certificates Issued	TÜV SÜD; Howard Wright_EN ISO 13485_Q5 077198 0010 Rev.00

Name Bruce Moller Position CEO

Signed Date 2021-06-09

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
2002 No. 618	Medical Devices Regulations 2002
2011/65/EU	Council Directive concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Directive 2017/2102
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN 60601-1: 2006	Medical Electrical Equipment - part 1: General Requirements for Basic Safety and Essential Performance.
EN 60601-2-52:2010	Medical Electrical Equipment - part 2-52: Particular Requirements for Basic Safety and Essential Performance of Medical Beds
EN 60601-1-11:2015	Medical Electrical Equipment -- part 1-11: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 60601-1-2:2007	General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
EN 60601-1-6:2010	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
ISO 7010:2011	Graphical Symbols - Safety Colours and Safety Signs - Registered Safety Signs
BS 7177:2008+A1:2011	Specification For Resistance To Ignition Of Mattresses, Mattress Pads, Divans And Bed Bases.
BS EN 597-1:1995	Furniture. Assessment Of The Ignitability Of Mattresses And Upholstered Bed Bases Ignition Source: Smouldering Cigarette.
BS EN 597-2:1995	Furniture. Assessment Of The Ignitability Of Mattresses And Upholstered Bed Bases Ignition Source: Match Flame Equivalent.
BS 6807:2006	Methods Of Test For Assessment Of Ignitability Of Mattresses, Upholstered Divans And Upholstered Bed Bases With Flaming Types Of Primary And Secondary Sources Of Ignition.
Oeko-Tex Standard 100	Harmful Chemicals in Fabric

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	EMDN Code	GMDN Code
ST2.1	Pacific Shower Bathing Trolley	Y093312 (SHOWER STRETCHERS)	31092
ST2.2	Pacific Shower Bathing Trolley Raised Bogie	Y093312 (SHOWER STRETCHERS)	31092

Version History

Version	Compiled by	Date	Description
1	D A Birnie	2011/7/11	First issue
2	D A Birnie	2019/07/30	Updated to Advena EC REP
3	D A Birnie	2021/05/10	Updated to MDR & UKCA