

Declaration of Conformity


FOR PACIFIC SHOWER BATHING TROLLEY

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices and 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

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Pacific Shower Bathing Trolley (PSBT)
Legal Manufacturer: (Name on Label)	HOWARD WRIGHT LIMITED PARAITE ROAD NEW PLYMOUTH 4312 NEW ZEALAND
Variants:	As per Appendix II (This document) – Product Listing/Schedule
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).
MD Directive Classification:	Class I, Rule 12
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Bruce Moller Position CEO

Signed  Date 2019/07/30

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.

EU Declaration of Conformity

Date: 2019/07/30

Appendix I – Applicable Standards

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

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
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
EN ISO 14971:2012	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
IEC60601-1-11:2015	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	GMDN Code
ST2.1	Pacific Shower Bathing Trolley	31092
ST2.2	Pacific Shower Bathing Trolley Raised Bogie	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 Advean EC REP