Declaration of Conformity

For the BES Healthcare Breezi Activity Chair Range.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Breezi Activity Chair
Legal Manufacturer: (Name on Label)	**BES Healthcare Ltd.** 131 South Liberty Lane Ashton Vale Bristol BS3 2SZ
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	506006659BAC001QP
Variants:	As per Annendix II (This document) – Product Listing / Schedule
Intended Purpose:	The Breezi Activity Chair Range, is intended to be used for younger patients with additional seating requirements, over and above those that can be met by conventional seating. The Breezi range can be adjusted to aid positioning and offer additional support for day-to-day activities.
MDR Classification:	Class I, by Rule 1, Annex VIII of the MDR.
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the Technical Documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name: Barend ter Haar Position: Director

Signed: Barend ter Haar 24/09/2024 Place: Bristol (UK).

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 manufacturers 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 (CS):

Standard / CS / Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 9001:2015	Quality Management Systems: Requirements
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical Devices. Symbols to be used with information to be supplied by the manufacturer – General requirements.
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing / Schedule

Catalogue Number / UDI-DI	Device Name	EMDN Code	EMDN Description
5060066590360	Teezi (Small, 39cm wide)	Y180999	CHAIRS / POSTURE SYSTEMS / SEAT POSITIONING AIDS - OTHER
5060066590346	Breezi (Medium, 42cm wide)	Y180999	CHAIRS / POSTURE SYSTEMS / SEAT POSITIONING AIDS - OTHER
5060066590391	Breezi Max (Large, 46cm wide)	Y180999	CHAIRS / POSTURE SYSTEMS / SEAT POSITIONING AIDS - OTHER

Version History

Version	Compiled by	Date	Description
1.0	R. Forder	28.03.2023	Initial release of document
2.0	R. Forder	24.09.2024	Inclusion of BUDI-DI and UDI-DI