Declaration of Conformity
for Belts

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices.

This EU declaration of conformity has been issued under the sole responsibility of the manufacturer.

The undersigned declares that the products described in this document are in conformity with the Medical Device Regulation EU/2017/745, and the CE Mark may be affixed.

General Product Name / Family Name:	Belt
Legal Manufacturer:	Welland Medical Ltd., Hydehurst Lane, Crawley, West Sussex RH10 9AS United Kingdom
EUDAMED Single Registration Number (SRN):	GB-MF-000033194
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Basic UDI-DI:	5024310A2R4S
Intended Use:	Provides extra security for the attachment of an ostomy appliance.
Medical Device Regulation Classification:	Class I, as per Annex VIII, Rule 1 and 18 of the (EU) 2017/745 regulation of the European Parliament and of the council of 5th April 2017 on medical devices
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
Medical Device Regulation Assessment Route:	Self-certification by Medical Device Regulation, Article 52, Annex II, Annex III; EC Declaration of Conformity in accordance to Article 19 and Annex IV;

Name Claude Sada

Position Managing Director

Signed _____

Date 24/06/2026

Place Crawley, West Sussex, UK

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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/ Common Specifications/ 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 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2025	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 20417:2026	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Product Code	Product Name	Product Description	GMDN Code	EMDN Code
Belts for UK				
BLTS01	Belt	Ostomy devices accessory, standard belt, 120cm	62951	A108006
BLTL01	Belt	Ostomy devices accessory, large belt, 145cm	62951	A108006
Belts for Export				
XBLTS01	Belt	Ostomy devices accessory, standard belt, 120cm	62951	A108006
XBLTL01	Belt	Ostomy devices accessory, large belt, 145cm	62951	A108006

Version History

Version	Compiled by	Date	Description
1.0	Beata Lesiak	21/06/2021	New format of the DOC
2.0	Mithila Merupula	16/03/2023	Added EUDAMED SRN number and deleted EN 1041:2008
3.0	Mithila Merupula	11/06/2025	CN 2381 discontinuation of the belt systems and updates to the standards.
4.0	Rosmi Xavier	02/06/2026	Updated applicable standards, added EMDN codes & updated Managing Director name to Claude Sada

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