Declaration of Conformity
for Secure Accessories

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:	Secure Accessories
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:	5024310A2KW (HydroFrame) 5024310A2W54 (UltraFrame)
Intended Use:	Provides extra security for an ostomy appliance.
Medical Device Regulation Classification:	Class I 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 with 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
HydroFrame®, Secure Accessories, flange extenders for UK				
WAFH33	HydroFrame®	Ostomy devices accessory, flange extender	46207	M04041503
HydroFrame®, Secure Accessories, flange extenders for Export				
XWAFH33	HydroFrame®	Ostomy devices accessory, flange extender	46207	M04041503
HydroFrame®, Secure Accessories, Mini flange extenders for UK				
WAFM33	HydroFrame®	Ostomy devices accessory, mini flange extender	46207	M04041503
HydroFrame®, Secure Accessories, Mini flange extenders for Export				
XWAFM33	HydroFrame®	Ostomy devices accessory, mini flange extender	46207	M04041503
HydroFrame®, Secure Accessories, flange extenders with Manuka honey for UK				
MHWAFH33	HydroFrame®	Ostomy devices accessory, flange extender with Manuka honey	46207	M04041503
HydroFrame®, Secure Accessories, flange extenders with Manuka honey for Export				
XMHWAFH33	HydroFrame®	Ostomy devices accessory, flange extender with Manuka honey	46207	M04041503
HydroFrame®, Secure Accessories, Mini flange extenders with Manuka honey for UK				
MHWAFM33	HydroFrame®	Ostomy devices accessory, mini flange extender with Manuka honey	46207	M04041503
HydroFrame®, Secure Accessories, Mini flange extenders with Manuka honey for Export				
XMHWAFM33	HydroFrame®	Ostomy devices accessory, mini flange extender with Manuka honey	46207	M04041503
UltraFrame®, Secure Accessories, flange extenders for UK				

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UFWAFH33	UltraFrame®	Ostomy devices accessory, flange extender	46207	M04041503
UltraFrame®, Secure Accessories, flange extenders for Export				
XUFWAFH33	UltraFrame®	Ostomy devices accessory, flange extender	46207	M04041503

Version History

Version	Compiled by	Date	Description
1.0	Beata Lesiak	13/05/2020	New format of the DOC
2.0	Beata Lesiak	11/08/2020	Products Listing updated. Updated with EU Authorised Representative details
3.0	Beata Lesiak	21/06/2021	Discontinuation of WAFH08 – CN2069. Removal of Belts and Belt Systems (a new DoC created for belts accessories). Updates to products descriptions. Transition to Medical Device Regulation EU/2017/745
4.0	James Airs	09/03/2023	Correcting Basic UDI-DI assignment, giving UltraFrame a separate Basic UDI-DI. Added SRN. Removed reference to standard that is not applied.
5.0	Mithila Merupula	19/03/2025	CR 2468
6.0	Mithila Merupula	15/05/2025	Updating Applicable Standards and adding rule to the classification.
7.0	Rosmi Xavier	02/06/2026	Updated applicable standards, added EMDN codes & updated Managing Director name to Claude Sada

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