Declaration of Conformity
for HyperSeal 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:	Hyperseal ®
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	5024310A1KU
Intended Use:	Protects the peristomal skin by providing extra security against leaks
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

Innovators in **Stomacare**

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Registered Office: Cavell House, Knaves Beech Way, Loudwater, High Wycombe,
Bucks HP10 9QY United Kingdom Registered in England 2170535 VAT No. 475 6939 87

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
Ostomy Device Accessory, HyperSeal®				
HWA300	HyperSeal®	Ostomy devices accessory, mouldable seals, 2.5mm thickness, 50mm diameter	46207	M04041503
Ostomy Device Accessory– HyperSeal®, with Manuka Honey (for UK)				
MHWA300	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 50mm diameter	46207	M04041503
MHWA310	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 60mm diameter	46207	M04041503
MHWA320	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 70mm diameter	46207	M04041503
MHWA330	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 80mm diameter	46207	M04041503
MHWA350	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 100mm diameter	46207	M04041503
MHWA400	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 4mm thickness, 50mm diameter	46207	M04041503
Ostomy Device Accessory– HyperSeal® with Manuka Honey (Export)				
XMHWA300	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 50mm diameter	46207	M04041503
XMHWA310	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 60mm diameter	46207	M04041503

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XMHWA320	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 70mm diameter	46207	M04041503
XMHWA330	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 80mm diameter	46207	M04041503
XMHWA350	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 100mm diameter	46207	M04041503
XMHWA400	HyperSeal®	Ostomy devices accessory, mouldable seals with Manuka honey, 4mm thickness, 50mm diameter	46207	M04041503

Version History

Version	Compiled by	Date	Description
1.0	Mithila Merupula	13/01/2025	New DoC created due to proposed changes in CR2468
2.0	Mithila Merupula	22/04/2025	Updating Basic UDI
3.0	Mithila Merupula	12/05/2025	Updating Applicable Standards and adding rule to the classification.
4.0	Mithila Merupula	07/08/2025	Updating product codes and product name
5.0	Rosmi Xavier	02/06/2026	Updated applicable standards, added EMDN codes & updated Managing Director name to Claude Sada

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