

# 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.

<b>General Product Name / Family Name:</b>	HyperSeal- Mouldable Seals
<b>Legal Manufacturer:</b>	Welland Medical Ltd., Hydehurst Lane, Crawley, West Sussex RH10 9AS United Kingdom
<b>EUDAMED Single Registration Number (SRN)</b>	GB-MF-000033194
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Basic UDI-DI</b>	5024310A1KU
<b>Intended Use:</b>	Protects the peristomal skin by providing extra security against leaks
<b>Medical Device Regulation Classification:</b>	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.
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta. SRN: MT-AR-000000234
<b>Medical Device Regulation Assessment Route:</b>	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 Samantha James

Position Managing Director

Signed 

Date 12/05/2025

Place Crawley, West Sussex, 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 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+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1-2018	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 20417:2021	Medical devices. Information to be supplied by the manufacturer

## Appendix II – Product Listing/Schedule

Product Code	Product Name	Product Description	GMDN Code
<b>HyperSeal<sup>®</sup>, Protect Accessories, mouldable seals for UK and Export</b>			
HWA300	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals, 2.5mm thickness, 50mm diameter	46207
HWA310	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals, 2.5mm thickness, 60mm diameter	46207
HWA320	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals, 2.5mm thickness, 70mm diameter	46207
HWA330	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals, 2.5mm thickness, 80mm diameter	46207
<b>HyperSeal<sup>®</sup>, Protect Accessories, mouldable seals with Manuka honey for UK</b>			
MHWA300	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 50mm diameter	46207
MHWA310	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 60mm diameter	46207
MHWA320	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 70mm diameter	46207
MHWA330	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 80mm diameter	46207
MHWA350	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 100mm diameter	46207
MHWA400	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 4mm thickness, 50mm diameter	46207

<b>HyperSeal<sup>®</sup>, Protect Accessories, mouldable seals with Manuka honey for Export</b>			
XMHWA300	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 50mm diameter	46207
XMHWA310	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 60mm diameter	46207
XMHWA320	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 70mm diameter	46207
XMHWA330	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 80mm diameter	46207
XMHWA350	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 2.5mm thickness, 100mm diameter	46207
XMHWA400	HyperSeal <sup>®</sup>	Ostomy devices accessory, mouldable seals with Manuka honey, 4mm thickness, 50mm diameter	46207

### 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.