# Declaration of Conformity
for Stoma Powder

## 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:** | Stoma Powder |
| **Legal Manufacturer:** | Welland Medical Ltd.,<br>Hydehurst Lane, Crawley,<br>West Sussex RH10 9AS<br>United Kingdom |
| **EUDAMED Single Registration Number (SRN):** | GB-MF-000033194 |
| **Variants:** | As per Appendix II (This document) – Product Listing/Schedule |
| **Basic UDI-DI:** | 5024310A1L4B |
| **Intended Use:** | Absorbs moisture to form a protective layer, helping to secure stoma adhesives. |
| **Medical Device Regulation Classification:** | Class I |
| **Notified Body:** | Not Applicable for Class I |
| **EU Authorised Representative:** | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta<br>SRN: MT-AR-000000234 |
| **Medical Device Regulation Assessment Route:** | Self-certification by Medical Device Regulation, Article 52, Annex II, Annex III;<br>EC Declaration of Conformity in accordance to Article 19 and Annex IV; |

**Name** Claude Sada

**Signed**

**Position** Managing Director

**Date** 24/06/2026

**Place** Crawley, West Sussex, UK



Innovators in **Stomacare**

**A CliniMed Group Company**
**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 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 10993-1:2009 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 15223-1:2016 | 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 |
|---|---|---|---|---|
| WPP025 | Stoma Powder | Ostomy device accessory, stoma powder, 25g | 46207 | M04041503 |

### Version History

| Version | Compiled by | Date | Description |
|---|---|---|---|
| 1.0 | Beata Lesiak | 13/05/2020 | New format of the DOC;<br>Transition to Medical Device Regulation EU/2017/745 |
| 2.0 | Mithila Merupula | 16/03/2023 | Added EUDAMED SRN number and deleted EN 1041:2008 |
| 3.0 | Rosmi Xavier | 02/06/2026 | Updated applicable standards, added EMDN codes & updated Managing Director name to Claude Sada |



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