Declaration of Conformity

for Stoma Powder Packaging

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19th December 2024 on packaging and packaging waste;

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 applicable requirements of the Packaging and Packaging Waste Regulation EU/2025/40

General Packaging Name	Stoma Powder Packaging
Packaging Code	FP0090 WPP025 PPR-INS-WPP
Legal Manufacturer:	Welland Medical Ltd., Hydehurst Lane, Crawley, West Sussex RH10 9AS United Kingdom
Variants:	As per Appendix II (This document) – Packaging Variants
Intended Use:	FP0090: Stoma powder bottle with dispenser nozzle & cap attached WPP025: Stoma powder carton PPR-INS-WPP: Stoma powder label
Packaging Classification:	Primary
EU Authorised Representative:	Not Applicable

Name Marc Clauson **Position** QARA Manager

Signed  **Date** 10 Aug 26

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

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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

Appendix I – Applicable Standards & Legislation

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
EU MDR 2017/745	Medical Device Regulation

Note: "No harmonised standards or common specifications conferring presumption of conformity under Regulation (EU) 2025/40 have been applied. Conformity has been demonstrated through the technical documentation in accordance with Annex VII."

Appendix II – Packaging Variants

Packaging Code	Packaging Description
FP0090	Primary packaging intended to contain and protect stoma powder and to facilitate controlled dispensing through an integrated nozzle. The attached cap provides reclosure and product protection during storage, transport, and use while maintaining the quality and integrity of the contents.
WPP025	Sales packaging intended to contain and protect the stoma powder bottle and to provide a surface for product identification, regulatory labelling, traceability information, and user information throughout distribution, sale, and use.
PPR-INS-WPP	Label intended to provide product identification, regulatory labelling, traceability information, and other essential product information.

Version History

Version	Compiled by	Date	Description
1	Frankie Overgage	07/08/2026	First version created

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