Declaration of Conformity

for Primary Packaging Labels

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	Primary Packaging Labels
Packaging Code	PPR-LAB-FG1 PPR-LAB-SM1 PPR-LAB-S45 PPR-LAB-S55 PPR-LAB-S70 PPR-LAB-F45 PPR-LAB-F55 PPR-LAB-F70 PPR-LAB-P01 PPR-LAB-P03 PPR-LAB-P04 PPR-LAB-P05 PPR-LAB-P07 PPR-LAB-P08 PPR-INS-WSP PPR-LAB-SHA OCO–LAB–B09
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:	To provide information, identification, traceability and communication relating to the packaged product and its packaging.
Packaging Classification:	Primary
EU Authorised Representative:	Not Applicable

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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

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

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
PPR-LAB-FG1	Finished Goods Label
PPR-LAB-SM1	Sample Label
PPR-LAB-S45	45mm Two-Piece Clampack Label
PPR-LAB-S55	55mm Two-Piece Clampack Label
PPR-LAB-S70	70mm Two-Piece Clampack Label
PPR-LAB-F45	45mm Two-Piece Box Label
PPR-LAB-F55	55mm Two-Piece Box Label
PPR-LAB-F70	70mm Two-Piece Box Label
PPR-LAB-P01	Hyperseal Label 65mm x 80mm
PPR-LAB-P03	WBS050, WBF050, WAD050, WAB050 Label 70mm x 30mm
PPR-LAB-P04	Stoma Paste Label 30mm x 130mm Ultraframe Label
PPR-LAB-P05	Hydroframe Label 50mm x 80mm
PPR-LAB-P07	WPP025 Stoma Powder Label 45mm x 120mm
PPR-LAB-P08	Hyperseal Label 67mm x 67mm
PPR-INS-WSP	Stoma Paste Tube Label
PPR-LAB-SHA	Mini Hydroframe Skin Health Alliance Sticker 20mm Circle

Version History

Version	Compiled by	Date	Description
1	Frankie Overgage	7/08/2026	First version created

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