Declaration of Conformity

for HyperSeal, Hydroframe & Stoma Paste Carton

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	HyperSeal, Hydroframe & Stoma Paste Carton
Packaging Codes	PCT-BOX-F32 PCT-BOX-F33 PCT-BOX-F40 PCT-BOX-F37 PCT-BOX-F30 PCT-BOX-F31 PCT-BOX-F34 PCT-BOX-F35 PCT-BOX-F38 PCT-BOX-F39 PCT-BOX-F18 PCT-BOX-F36
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:	Printed carton intended to contain, protect, identify, and provide information for ostomy accessories during storage, transport, and use.
Packaging Classification:	Primary
EU Authorised Representative:	Not Applicable

Name Marc Clauson **Position** QARA Manager

Signed **Date** 10 Aug 26.

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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
PCT-BOX-F32	Printed Packaging for Hydroframe: Manuka Honey Carton 20 Pack
PCT-BOX-F33	Printed Packaging for Hydroframe: Manuka Honey Carton 10 Pack
PCT-BOX-F40	Printed Packaging for Hydroframe: Carton 10 Pack
PCT-BOX-F37	Printed Packaging for Mini Hydroframe Carton
PCT-BOX-F30	Printed Packaging for HyperSeal: Hyperseal Box Manuka Honey 60mm 30 Pack
PCT-BOX-F31	Printed Packaging for HyperSeal: Hyperseal Box Manuka Honey 70mm & 80mm 30 Pack
PCT-BOX-F34	Printed Packaging for HyperSeal: Hyperseal 50mm Manuka Honey Carton 10 Pack
PCT-BOX-F35	Printed Packaging for HyperSeal: Hyperseal 50mm Manuka Honey Carton 20 Pack
PCT-BOX-F38	Printed Packaging for HyperSeal: Hyperseal Carton 50mm 20 Pack
PCT-BOX-F39	Printed Packaging for HyperSeal Hyperseal Carton 50mm 30 Pack
PCT-BOX-F18	Printed Packaging for HyperSeal: Hyperseal 100mm Carton 5 Pack
PCT-BOX-F36	Printed Packaging for Stoma Paste Carton

Version History

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

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