Declaration of Conformity

for Stoma Paste Tube

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 Paste Tube
Packaging Code	95591
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:	The tube is intended to serve as primary packaging for stoma paste. It is designed to contain and protect the product throughout its shelf life, facilitate hygienic dispensing by the user, and provide a barrier against contamination, moisture loss, and environmental influences during storage, transportation, and use.
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

Appendix I – Applicable Standards & Legislation

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

Standard/Document Name	Description

Innovators in **Stomacare**

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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
95591	Stoma Paste Tube - The tube provides a sealed container that maintains product integrity during storage, transportation, and normal use while enabling controlled dispensing of the contents.

Version History

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

Innovators in **Stomacare**

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