Declaration of Conformity

for Barrier Film Wipe 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.

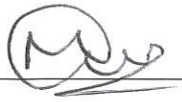
The undersigned declares that the products described in this document are in conformity with the applicable requirements of the Packaging and Packaging Waste Regulation EU/2025/40

General Packaging Name	Barrier Film Wipe Packaging
Packaging Code	RLS006999 RLS007000 RLS007012 CAR001476 CAR001475 CAR001477 CAR001539
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:	RLS006999/RLS007000/RLS007012 - The sachet is intended to contain, protect, and preserve a single barrier film wipe throughout its specified shelf life, maintaining product integrity until the point of use and enabling safe storage, transportation, distribution, and presentation of the wipe to the user. CAR001476/CAR001475/CAR001477 /CAR001539 - To contain, protect, identify, and present multiple individually packaged Barrier Film Wipes throughout the supply chain and provide product and regulatory information to the user at the point of sale and use.
Packaging Classification:	Primary
EU Authorised Representative:	Not Applicable

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

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
RLS006999 RLS007000 RLS007012	The sachet is a sealed primary packaging component designed to contain a single pre-moistened barrier wipe. The sachet provides a barrier against environmental factors that may affect the quality of the wipe, such as moisture loss, contamination, and physical damage, during storage, transportation, and handling.
CAR001476 CAR001475 CAR001477 CAR001539	The carton is a packaging component designed to contain and protect multiple individually packaged Barrier Film Wipes. The carton facilitates the storage, handling, transportation, distribution, and presentation of the product while maintaining the integrity of the enclosed sachets. It also provides identification, traceability, regulatory information, instructions for use, and other required labelling.

Version History

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

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