Declaration of Conformity

for Peel Seal Pouch

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	Peel Seal Pouch
Packaging Code	RRA-POU-W01
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 Peel Seal Pouch is intended for use as the internal packaging for finished post-operative products (i.e. POP, WOP, SOP and NOP) in order to prevent exposure to potential contaminants during storage
Packaging Classification:	Primary
EU Authorised Representative:	Not Applicable

Name Marc Clauson **Position** QARA Manager

Signed _____ **Date** 20 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

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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
RRA-POU-W01	Peel Seal Pouch - manufactured from two primary layers consisting of a PET/PE film and 60g Ethypel Premium paper. These layers are then hermetically sealed along three sides via a heat seal.

Version History

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

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