Declaration of Conformity

for Universal APET Clam Pack

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	Universal APET Clam Pack
Packaging Code	PCT-PAC-A27 PCT-PAC-A28 PCT-PAC-A29
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:	Clam packs are intended to contain, protect and identify 2-piece ostomy flanges.
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
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
PCT-PAC-A27	45mm Universal APET Clam pack
PCT-PAC-A28	55mm Universal APET Clam pack
PCT-PAC-A29	70mm Universal APET Clam pack

Version History

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

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