Declaration of Conformity

for Welland Barrier Film

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices;

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 Medical Device Regulation EU/2017/745, and the CE Mark may be affixed.

General Product Name / Family Name:	Welland Barrier Film
Legal Manufacturer:	Welland Medical Ltd., Hydehurst Lane, Crawley, West Sussex RH10 9AS United Kingdom
EUDAMED Single Registration Number (SRN)	GB-MF-000033194
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Basic UDI-DI:	5024310A1K49 (wipes) 5024310A1V4X (spray)
Intended Use:	Protects skin from contact with stoma output and adhesive related skin stripping.
Medical Device Regulation Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta SRN: MT-AR-000000234
Medical Device Regulation Assessment Route:	Self-certification by Medical Device Regulation, Article 52, Annex II, Annex III; EC Declaration of Conformity in accordance to Article 19 and Annex IV;

Name Samantha Jackson **Position** Managing Director

Signed **Date** 15/03/2023

Place Crawley, West Sussex, UK

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

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

Standard/ Common Specifications/ Document Name	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Appendix II – Product Listing/Schedule

Product Code	Product Name	Product Description	GMDN Code
Welland Barrier Film wipes			
WBF050	WBF®	Ostomy device accessory, no sting, skin barrier wipe, 50 wipes	58978
WBF060	WBF®	Ostomy device accessory, no sting, skin barrier wipe, 60 wipes	58978
Welland Barrier Film spray			
WBS050	WBF®	Ostomy device accessory, no sting, barrier spray, 50ml	58978

Version History

Version	Compiled by	Date	Description
1.0	Beata Lesiak	13/05/2020	New format of the DOC; Transition to Medical Device Regulation EU/2017/745
2.0	James Airs	13/03/2023	Correcting Basic UDI-DI assignment, giving active sprays a separate Basic UDI-DI. Added SRN. Removed reference to standard that is not applied.