Declaration of Conformity
for WBF®

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

This declaration of conformity has been issued under the sole responsibility of the manufacturer.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	WBF®
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
Intended Use:	Protects skin from contact with stoma output and adhesive related skin stripping.
Medical Device Classification:	Class I Sterile
Notified Body:	SGS Belgium NV, Notified Body 1639 SGS House, Noorderlaan 87, 2030, Antwerpen, Belgium
CE Certificate Reference:	GB20/965309
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
MDD Conformity Assessment Route:	EC Declaration by the Notified Body to Annex V of the Medical Device Directive.

Name Claude Sada **Position** Managing Director

Signed _____ **Date** 24/06/2026

Place Crawley, West Sussex, UK

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

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/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2025	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 11137-1:2025	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
EN ISO 11137-2:2015+A1:2023	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 20417:2026	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Product Code	Product Name	Product Description	GMDN Code	EMDN Code
WBF100	WBF®	Ostomy device accessory, no sting skin barrier wipe, sterile, 30 wipes	58978	M0499

Version History

Version	Compiled by	Date	Description
1.0	Kim Dodman	13/04/2015	New DOC082 created;
2.0	Kim Dodman	22/06/2015	Addition of comment regarding LRQA as the single notified body (Ref: DOC082)
3.0	Kim Dodman	14/01/2016	A typographical error corrected (Ref: DOC082)
4.0	Beata Lesiak	26/04/2017	Updated with LRQA logo (Ref: DOC082)
5.0	Beata Lesiak	30/03/2020	Notified Body details updated (moved from LRQA to SGS UK) (Ref: DOC082)
6.0	Beata Lesiak	21/05/2020	New format of the Declaration of Conformity document (DOC082 replaced with DOC– WBF); Notified Body details updated (transferred from SGS UK to SGS Belgium);

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

7.0	Beata Lesiak	13/08/2020	General Product name and description within Version History updated; Updated with NB address, CE Certificate Reference and EU Authorised Representative details;
8.0	Mithila Merupula	16/03/2023	Added EUDAMED SRN number and deleted EN 1041:2008
9.0	James Airs	20/12/2023	Changed GMDN from 58979 to 58978 because 58979 has been made obsolete. 58978 now covers sterile and non-sterile versions. Added Place to signature. Updated Managing Director's name.
10.0	Rosmi Xavier	17/06/2026	Updated Managing Director's name, applicable standards and added EMDN code.

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