Declaration of Conformity
for Flair®

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:	Flair®
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:	5024310X977E
Intended Use:	For collecting stoma output.
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 Claude Sada **Position** Managing Director

Signed **Date** 24/06/2026

Place Crawley, West Sussex, UK

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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
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 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
Flair®, Ostomy Device One-Piece, Closed				
XFLC513	Flair®	Ostomy device one-piece, closed, maxi pouch size, 13mm starter hole	31066	A10019
XFLC525	Flair®	Ostomy device one-piece, closed, maxi pouch size, 25mm pre-cut stoma hole	31066	A10019
XFLC532	Flair®	Ostomy device one-piece, closed, maxi pouch size, 32mm pre-cut stoma hole	31066	A10019
XFLC538	Flair®	Ostomy device one-piece, closed, maxi pouch size, 38mm pre-cut stoma hole	31066	A10019
XFLC544	Flair®	Ostomy device one-piece, closed, maxi pouch size, 44mm pre-cut stoma hole	31066	A10019
XFLC713	Flair®	Ostomy device one-piece, closed, maxi pouch size, 13mm starter hole	31066	A10019
XFLC725	Flair®	Ostomy device one-piece, closed, maxi pouch size, 25mm pre-cut stoma hole	31066	A10019
XFLC732	Flair®	Ostomy device one-piece, closed, maxi pouch size, 32mm pre-cut stoma hole	31066	A10019
XFLC738	Flair®	Ostomy device one-piece, closed, maxi pouch size, 38mm pre-cut stoma hole	31066	A10019
XFLC744	Flair®	Ostomy device one-piece, closed, maxi pouch size, 44mm pre-cut stoma hole	31066	A10019
Flair®, Ostomy Device One-Piece, Closed				
XFCV513	Flair®	Ostomy device one-piece, closed, oval flange, 13mm starter hole	31066	A10019
Flair®, Ostomy Device One-Piece, Drainable				
XFLD513	Flair®	Ostomy device one-piece, drainable, maxi pouch size, 13mm starter hole	31075	A100302
XFLD532	Flair®	Ostomy device one-piece, drainable, maxi pouch size, 32mm pre-cut stoma hole	31075	A100302

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Flair®, Ostomy Device One-Piece, Drainable				
XFLI713	Flair®	Ostomy device one-piece, drainable, (no integral outlet), 13mm starter hole	31075	A100302
Flair® Convex, Ostomy Device One-Piece, Closed				
XNCM513	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 13mm starter hole	31066	A100199
XNCM525	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 25mm pre-cut stoma hole	31066	A100199
XNCM529	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 29mm pre-cut stoma hole	31066	A100199
XNCM532	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 32mm pre-cut stoma hole	31066	A100199
XNCM535	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 35mm pre-cut stoma hole	31066	A100199
XNCM713	Flair® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 13mm starter hole	31066	A100199
XNCL513	Flair® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 13mm starter hole	31066	A100199
XNCL535	Flair® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 35mm pre-cut stoma hole	31066	A100199
XNCL538	Flair® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 38mm pre-cut stoma hole	31066	A100199
XNCL544	Flair® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 44mm pre-cut stoma hole	31066	A100199
XNCL713	Flair® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 13mm starter hole	31066	A100199
Flair® Convex, Ostomy Device One-Piece, Drainable				
XNDM513	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 13mm starter hole	31075	A100302
XNDM525	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 25mm pre-cut stoma hole	31075	A100302
XNDM529	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 29mm pre-cut stoma hole	31075	A100302
XNDM532	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 32mm pre-cut stoma hole	31075	A100302
XNDM535	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 35mm pre-cut stoma hole	31075	A100302
XNDM713	Flair® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 13mm starter hole	31075	A100302
XNDL513	Flair® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 13mm starter hole	31075	A100302

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XNDL535	Flair® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 35mm pre-cut stoma hole	31075	A100302
XNDL538	Flair® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 38mm pre-cut stoma hole	31075	A100302
XNDL544	Flair® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 44mm pre-cut stoma hole	31075	A100302
XNDL713	Flair® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 13mm starter hole	31075	A100302
Flair® Curvex, Ostomy Device One-Piece, Drainable				
XCDS513	Flair® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 13mm starter hole	31075	A100302
XCDS713	Flair® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 13mm starter hole	31075	A100302
XCDM513	Flair® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 13mm starter hole	31075	A100302
XCDM525	Flair® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 25mm pre-cut stoma hole	31075	A100302
XCDM532	Flair® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 32mm pre-cut stoma hole	31075	A100302
XCDM713	Flair® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 13mm starter hole	31075	A100302
XCDL513	Flair® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 13mm starter hole	31075	A100302
XCDL532	Flair® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 32mm pre-cut stoma hole	31075	A100302
XCDL538	Flair® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 38mm pre-cut stoma hole	31075	A100302
XCDL713	Flair® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 13mm starter hole	31075	A100302
Flair® 2, Ostomy Device Two-Pieces, Closed				
XA2C445	Flair® 2	Ostomy device two-piece, closed, midi pouch size, 45mm ring size	31067	A100299
XA2C455	Flair® 2	Ostomy device two-piece, closed, midi pouch size, 55mm ring size	31067	A100299
XA2C645	Flair® 2	Ostomy device two-piece, closed, midi pouch size, 45mm ring size	31067	A100299
XA2C655	Flair® 2	Ostomy device two-piece, closed, midi pouch size, 55mm ring size	31067	A100299
XA2C545	Flair® 2	Ostomy device two-piece, closed, maxi pouch size, 45mm ring size	31067	A100299
XA2C555	Flair® 2	Ostomy device two-piece, closed, maxi pouch size, 55mm ring size	31067	A100299
XA2C745	Flair® 2	Ostomy device two-piece, closed, maxi pouch size, 45mm ring size	31067	A100299
XA2C755	Flair® 2	Ostomy device two-piece, closed, maxi pouch size, 55mm ring size	31067	A100299
XA2C145	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 45mm ring size	31067	A100299

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XA2C155	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 55mm ring size	31067	A100299
XA2C170	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 70mm ring size	31067	A100299
XA2C345	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 45mm ring size	31067	A100299
XA2C355	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 55mm ring size	31067	A100299
XA2C370	Flair® 2	Ostomy device two-piece, closed, maxi plus pouch size, 70mm ring size	31067	A100299
Flair® 2, Ostomy Device Two-Pieces, Drainable				
XA2D445	Flair® 2	Ostomy device two-piece, drainable, midi pouch size, 45mm ring size	31076	A100302
XA2D455	Flair® 2	Ostomy device two-piece, drainable, midi pouch size, 55mm ring size	31076	A100302
XA2D645	Flair® 2	Ostomy device two-piece, drainable, midi pouch size, 45mm ring size	31076	A100302
XA2D655	Flair® 2	Ostomy device two-piece, drainable, midi pouch size, 55mm ring size	31076	A100302
XA2D545	Flair® 2	Ostomy device two-piece, drainable, maxi pouch size, 45mm ring size	31076	A100302
XA2D555	Flair® 2	Ostomy device two-piece, drainable, maxi pouch size, 55mm ring size	31076	A100302
XA2D745	Flair® 2	Ostomy device two-piece, drainable, maxi pouch size, 45mm ring size	31076	A100302
XA2D755	Flair® 2	Ostomy device two-piece, drainable, maxi pouch size, 55mm ring size	31076	A100302
XA2D145	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 45mm ring size	31076	A100302
XA2D155	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 55mm ring size	31076	A100302
XA2D170	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 70mm ring size	31076	A100302
XA2D345	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 45mm ring size	31076	A100302
XA2D355	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 55mm ring size	31076	A100302
XA2D370	Flair® 2	Ostomy device two-piece, drainable, maxi plus pouch size, 70mm ring size	31076	A100302
Flair® 2, Ostomy Device Two-Pieces, Drainable				
XA2Z545	Flair® 2	Ostomy device two-piece, drainable (without filter), maxi pouch size, 45mm ring size	31076	A100302
XA2Z555	Flair® 2	Ostomy device two-piece, drainable (without filter), maxi pouch size, 55mm ring size	31076	A100302
XA2Z170	Flair® 2	Ostomy device two-piece, drainable (without filter), maxi plus pouch size, 70mm ring size	31076	A100302
Flair® 2, Ostomy Device Two-Pieces, Urostomy				
XP2U545	Flair® 2	Ostomy device two-piece, urostomy, 45mm ring size	31069	A100299
XP2U555	Flair® 2	Ostomy device two-piece, urostomy, 55mm ring size	31069	A100299
XP2U745	Flair® 2	Ostomy device two-piece, urostomy, 45mm ring size	31069	A100299
XP2U755	Flair® 2	Ostomy device two-piece, urostomy, 55mm ring size	31069	A100299

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Flair® 2, Ostomy Device Two-Pieces, Flat Flange				
XA2F413	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 13mm stoma hole	48159	A108001
XA2F425	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 25mm pre-cut stoma hole	48159	A108001
XA2F429	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 29mm pre-cut stoma hole	48159	A108001
XA2F432	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 32mm pre-cut stoma hole	48159	A108001
XA2F435	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 35mm pre-cut stoma hole	48159	A108001
XA2F438	Flair® 2	Ostomy device two-piece, flat flange, 45mm ring size, 38mm pre-cut stoma hole	48159	A108001
XA2F513	Flair® 2	Ostomy device two-piece, flat flange, 55mm ring size, 13mm stoma hole	48159	A108001
XA2F538	Flair® 2	Ostomy device two-piece, flat flange, 55mm ring size, 38mm pre-cut stoma hole	48159	A108001
XA2F544	Flair® 2	Ostomy device two-piece, flat flange, 55mm ring size, 44mm pre-cut stoma hole	48159	A108001
XA2F713	Flair® 2	Ostomy device two-piece, flat flange, 70mm ring size, 13mm stoma hole	48159	A108001
Flair® 2, Ostomy Device Two-Pieces, Convex Flange				
XN2F413	Flair® 2	Ostomy device two-pieces convex flange, 45mm ring size, 13mm stoma hole	48158	A108001
XN2F513	Flair® 2	Ostomy device two-piece, convex flange, 55mm ring size, 13mm stoma hole	48158	A108001
XN2F525	Flair® 2	Ostomy device two-piece, convex flange, 55mm ring size, 25mm pre-cut stoma hole	48158	A108001
XN2F529	Flair® 2	Ostomy device two-piece, convex flange, 55mm ring size, 29mm pre-cut stoma hole	48158	A108001
XN2F532	Flair® 2	Ostomy device two-piece, convex flange, 55mm ring size, 32mm pre-cut stoma hole	48158	A108001
XN2F535	Flair® 2	Ostomy device two-piece, convex flange, 55mm ring size, 35mm pre-cut stoma hole	48158	A108001
XN2F713	Flair® 2	Ostomy device two-piece, convex flange, 70mm ring size, 13mm stoma hole	48158	A108001
Flair® 2, Ostomy Device Two-Pieces, Urostomy Flange				
XPU2F413	Flair® 2	Ostomy device two-piece, urostomy flange, 45mm ring size, 13mm starter hole	48159	A108001
XPU2F419	Flair® 2	Ostomy device two-pieces urostomy flange, 45mm ring size, 19mm pre-cut stoma hole	48159	A108001
XPU2F422	Flair® 2	Ostomy device two-piece, urostomy flange, 45mm ring size, 22mm pre-cut stoma hole	48159	A108001
XPU2F425	Flair® 2	Ostomy device two-piece, urostomy flange, 45mm ring size, 25mm pre-cut stoma hole	48159	A108001
XPU2F429	Flair® 2	Ostomy device two-piece, urostomy flange, 45mm ring size, 29mm pre-cut stoma hole	48159	A108001
XPU2F432	Flair® 2	Ostomy device two-piece, urostomy flange, 45mm ring size, 32mm pre-cut stoma hole	48159	A108001
XPU2F435	Flair® 2	Ostomy device two-pieces urostomy flange, 45mm ring size, 35mm pre-cut stoma hole	48159	A108001
XPU2F438	Flair® 2	Ostomy device two-pieces urostomy flange, 45mm ring size, 38mm pre-cut stoma hole	48159	A108001
XPU2F513	Flair® 2	Ostomy device two-piece, urostomy flange, 55mm ring size, 13mm starter hole	48159	A108001

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Flair®, Ostomy Device One-Piece, Closed, with Collars (for Spain only)				
XFMC525C	Flair®	Ostomy device one-piece, closed, midi pouch size, 25mm pre-cut stoma hole, collars included	31066	A100199
XFMC532C	Flair®	Ostomy device one-piece, closed, midi pouch size, 32mm pre-cut stoma hole, collars included	31066	A100199
XFMC538C	Flair®	Ostomy device one-piece, closed, midi pouch size, 38mm pre-cut stoma hole, collars included	31066	A100199
XFMC713C	Flair®	Ostomy device one-piece, closed, midi pouch size, clear, 13mm starter hole, collars included	31066	A100199
XFLC713C	Flair®	Ostomy device one-piece, closed, maxi pouch size, clear, 13mm starter hole, collars included	31066	A100199

Version History

Version	Compiled by	Date	Description
1.0	Beata Lesiak	13/05/2020	New format of the DOC
2.0	Beata Lesiak	11/08/2020	Products for Spain added (CN2044);
3.0	Beata Lesiak	12/08/2020	Updated with EU Authorised Representative details
4.0	Arnya Traher	18/03/2020	Version 3.0 cancelled due to error in approval cycle. No other changes from Version 3.0
5.0	Beata Lesiak	01/06/2021	Transition to Medical Device Regulation EU/2017/745
6.0	Mithila Merupula	16/03/2023	Added EUDAMED SRN number and deleted EN 1041:2008
7.0	Rosmi Xavier	29/05/2026	Updated applicable standards, removed discontinued codes, added EMDN codes & updated Managing Director name to Claude Sada

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