

Declaration of Conformity

for Flair Active®



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 Active®
Legal Manufacturer:	Welland Medical Ltd., Hydehurst Lane, Crawley, West Sussex RH10 9AS United Kingdom
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Basic UDI-DI:	5024310X9478
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 Samantha Jackson

Position Managing Director

Signed

Date 21/6/2021

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 1041:2008	Information supplied by the manufacturer of medical devices
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
Flair Active®, Ostomy Device One-Piece, Closed			
XPLC513	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 13mm starter hole	31066
XPLC525	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 25mm pre-cut stoma hole	31066
XPLC529	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 29mm pre-cut stoma hole	31066
XPLC532	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 32mm pre-cut stoma hole	31066
XPLC535	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 35mm pre-cut stoma hole	31066
XPLC538	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 38mm pre-cut stoma hole	31066
XPLC544	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 44mm pre-cut stoma hole	31066
XPLC713	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 13mm starter hole	31066
XPLC725	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 25mm pre-cut stoma hole	31066
XPLC729	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 29mm pre-cut stoma hole	31066
XPLC732	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 32mm pre-cut stoma hole	31066
XPLC735	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 35mm pre-cut stoma hole	31066
XPLC738	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 38mm pre-cut stoma hole	31066
XPLC744	Flair Active®	Ostomy device one-piece, closed, maxi pouch size, 44mm pre-cut stoma hole	31066
XPMC513	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 13mm starter hole	31066
XPMC525	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 25mm pre-cut stoma hole	31066
XPMC529	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 29mm pre-cut stoma hole	31066

XPMC532	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 32mm pre-cut stoma hole	31066
XPMC535	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 35mm pre-cut stoma hole	31066
XPMC538	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 38mm pre-cut stoma hole	31066
XPMC544	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 44mm pre-cut stoma hole	31066
XPMC713	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 13mm starter hole	31066
XPMC725	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 25mm pre-cut stoma hole	31066
XPMC729	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 29mm pre-cut stoma hole	31066
XPMC732	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 32mm pre-cut stoma hole	31066
XPMC735	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 35mm pre-cut stoma hole	31066
XPMC738	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 38mm pre-cut stoma hole	31066
XPMC744	Flair Active®	Ostomy device one-piece, closed, midi pouch size, 44mm pre-cut stoma hole	31066
Flair Active®, Ostomy Device One-Piece, Drainable			
XPLD513	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 13mm starter hole	31075
XPLD525	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 25mm pre-cut stoma hole	31075
XPLD529	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 29mm pre-cut stoma hole	31075
XPLD532	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 32mm pre-cut stoma hole	31075
XPLD535	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 35mm pre-cut stoma hole	31075
XPLD538	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 38mm pre-cut stoma hole	31075
XPLD544	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 44mm pre-cut stoma hole	31075
XPLD713	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 13mm starter hole	31075
XPLD725	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 25mm pre-cut stoma hole	31075
XPLD729	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 29mm pre-cut stoma hole	31075
XPLD732	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 32mm pre-cut stoma hole	31075
XPLD735	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 35mm pre-cut stoma hole	31075
XPLD738	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 38mm pre-cut stoma hole	31075
XPLD744	Flair Active®	Ostomy device one-piece, drainable, maxi pouch size, 44mm pre-cut stoma hole	31075
XPMD513	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 13mm starter hole	31075
XPMD525	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 25mm pre-cut stoma hole	31075

XPMD529	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 29mm pre-cut stoma hole	31075
XPMD532	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 32mm pre-cut stoma hole	31075
XPMD535	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 35mm pre-cut stoma hole	31075
XPMD538	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 38mm pre-cut stoma hole	31075
XPMD544	Flair Active®	Ostomy device one-piece, drainable, midi pouch size, 44mm pre-cut stoma hole	31075
Flair Active®, Ostomy Device One-Piece, Drainable			
XPLZ513	Flair Active®	Ostomy device one-piece, drainable, without filter, maxi pouch size, 13mm starter hole	31075
XPLZ713	Flair Active®	Ostomy device one-piece, drainable, without filter, maxi pouch size, 13mm starter hole	31075
Flair Active®, Ostomy Device One-Piece, Urostomy			
XPUR513	Flair Active®	Ostomy device one-piece, urostomy, 13mm starter hole	64583
XPUR519	Flair Active®	Ostomy device one-piece, urostomy, 19mm pre-cut stoma hole	64583
XPUR522	Flair Active®	Ostomy device one-piece, urostomy, 22mm pre-cut stoma hole	64583
XPUR525	Flair Active®	Ostomy device one-piece, urostomy, 25mm pre-cut stoma hole	64583
XPUR529	Flair Active®	Ostomy device one-piece, urostomy, 29mm pre-cut stoma hole	64583
XPUR532	Flair Active®	Ostomy device one-piece, urostomy, 32mm pre-cut stoma hole	64583
XPUR535	Flair Active®	Ostomy device one-piece, urostomy, 35mm pre-cut stoma hole	64583
XPUR538	Flair Active®	Ostomy device one-piece, urostomy, 38mm pre-cut stoma hole	64583
XPUR713	Flair Active®	Ostomy device one-piece, urostomy, 13mm starter hole	64583
XPUR719	Flair Active®	Ostomy device one-piece, urostomy, 19mm pre-cut stoma hole	64583
XPUR722	Flair Active®	Ostomy device one-piece, urostomy, 22mm pre-cut stoma hole	64583
XPUR725	Flair Active®	Ostomy device one-piece, urostomy, 25mm pre-cut stoma hole	64583
XPUR729	Flair Active®	Ostomy device one-piece, urostomy, 29mm pre-cut stoma hole	64583
XPUR732	Flair Active®	Ostomy device one-piece, urostomy, 32mm pre-cut stoma hole	64583
XPUR735	Flair Active®	Ostomy device one-piece, urostomy, 35mm pre-cut stoma hole	64583
XPUR738	Flair Active®	Ostomy device one-piece, urostomy, 38mm pre-cut stoma hole	64583
Flair Active®, Ostomy Device One-Piece, Paediatric			
XMCS513	Flair Active®	Ostomy device one-piece, closed, paediatric, medium bag	31066
XMDS513	Flair Active®	Ostomy device one-piece, drainable, paediatric, medium bag	31075
Flair Active® Xtra, Ostomy Device One-Piece, Closed			

XPFM519	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 19mm stoma hole	31066
XPFM525	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 25mm stoma hole	31066
XPFM529	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 29mm stoma hole	31066
XPFM532	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 32mm stoma hole	31066
XPFM535	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 35mm stoma hole	31066
XPFM538	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 38mm stoma hole	31066
XPFM544	Flair Active® Xtra	Ostomy device one-piece, closed, midi pouch size, flushable liner, 44mm stoma hole	31066
XPFL519	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 19mm stoma hole	31066
XPFL525	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 25mm stoma hole	31066
XPFL529	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 29mm stoma hole	31066
XPFL532	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 32mm stoma hole	31066
XPFL535	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 35mm stoma hole	31066
XPFL538	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 38mm stoma hole	31066
XPFL544	Flair Active® Xtra	Ostomy device one-piece, closed, maxi pouch size, flushable liner, 44mm stoma hole	31066
Flair Active® Convex, Ostomy Device One-Piece, Closed			
XPNCM513	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 13mm starter hole	31066
XPNCM519	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 19mm pre-cut stoma hole	31066
XPNCM522	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 22mm pre-cut stoma hole	31066
XPNCM525	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 25mm pre-cut stoma hole	31066
XPNCM529	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 29mm pre-cut stoma hole	31066
XPNCM532	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 32mm pre-cut stoma hole	31066
XPNCM535	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 35mm pre-cut stoma hole	31066
XPNCM713	Flair Active® Convex	Ostomy device one-piece, closed, convex, medium plateau (35mm), 13mm starter hole	31066

XPNCL513	Flair Active® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 13mm starter hole	31066
XPNCL535	Flair Active® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 35mm pre-cut stoma hole	31066
XPNCL538	Flair Active® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 38mm pre-cut stoma hole	31066
XPNCL544	Flair Active® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 44mm pre-cut stoma hole	31066
XPNCL713	Flair Active® Convex	Ostomy device one-piece, closed, convex, large plateau (48mm), 13mm starter hole	31066
Flair Active® Convex, Ostomy Device One-Piece, Drainable			
XPNDM513	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 13mm starter hole	31075
XPNDM519	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 19mm pre-cut stoma hole	31075
XPNDM522	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 22mm pre-cut stoma hole	31075
XPNDM525	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 25mm pre-cut stoma hole	31075
XPNDM529	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 29mm pre-cut stoma hole	31075
XPNDM532	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 32mm pre-cut stoma hole	31075
XPNDM535	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 35mm pre-cut stoma hole	31075
XPNDM713	Flair Active® Convex	Ostomy device one-piece, drainable, convex, medium plateau (35mm), 13mm starter hole	31075
XPNDL513	Flair Active® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 13mm starter hole	31075
XPNDL535	Flair Active® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 35mm pre-cut stoma hole	31075
XPNDL538	Flair Active® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 38mm pre-cut stoma hole	31075
XPNDL544	Flair Active® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 44mm pre-cut stoma hole	31075
XPNDL713	Flair Active® Convex	Ostomy device one-piece, drainable, convex, large plateau (48mm), 13mm starter hole	31075
Flair Active® Convex, Ostomy Device One-Piece, Urostomy			
XPNUS513	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, small plateau (25mm), 13mm starter hole	64583
XPNUS519	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, small plateau (25mm), 19mm pre-cut stoma hole	64583
XPNUS522	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, small plateau (25mm), 22mm pre-cut stoma hole	64583
XPNUS525	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, small plateau (25mm), 25mm pre-cut stoma hole	64583

XPNU5713	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, small plateau (25mm), 13mm starter hole	64583
XPNUM513	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 13mm starter hole	64583
XPNUM525	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 25mm pre-cut stoma hole	64583
XPNUM529	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 29mm pre-cut stoma hole	64583
XPNUM532	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 32mm pre-cut stoma hole	64583
XPNUM535	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 35mm pre-cut stoma hole	64583
XPNUM713	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, medium plateau (35mm), 13mm starter hole	64583
XPNU513	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, large plateau (48mm), 13mm starter hole	64583
XPNU532	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, large plateau (48mm), 32mm pre-cut stoma hole	64583
XPNU538	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, large plateau (48mm), 38mm pre-cut stoma hole	64583
XPNU713	Flair Active® Convex	Ostomy device one-piece, urostomy, convex, large plateau (48mm), 13mm starter hole	64583
Flair Active® Curvex, Ostomy Device One-Piece, Closed			
XPCCS513	Flair Active® Curvex	Ostomy device one-piece, closed, small plateau (25mm), 13mm starter hole	31066
XPCCS519	Flair Active® Curvex	Ostomy device one-piece, closed, small plateau (25mm), 19mm pre-cut stoma hole	31066
XPCCS522	Flair Active® Curvex	Ostomy device one-piece, closed, small plateau (25mm), 22mm pre-cut stoma hole	31066
XPCCS713	Flair Active® Curvex	Ostomy device one-piece, closed, small plateau (25mm), 13mm starter hole	31066
XPCCM513	Flair Active® Curvex	Ostomy device one-piece, closed, medium plateau (32mm), 13mm starter hole	31066
XPCCM525	Flair Active® Curvex	Ostomy device one-piece, closed, medium plateau (32mm), 25mm pre-cut stoma hole	31066
XPCCM529	Flair Active® Curvex	Ostomy device one-piece, closed, medium plateau (32mm), 29mm pre-cut stoma hole	31066
XPCCM532	Flair Active® Curvex	Ostomy device one-piece, closed, medium plateau (32mm), 32mm pre-cut stoma hole	31066
XPCCM713	Flair Active® Curvex	Ostomy device one-piece, closed, medium plateau (32mm), 13mm starter hole	31066
XPCCCL513	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 13mm starter hole	31066
XPCCCL532	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 32mm pre-cut stoma hole	31066

XPCCL535	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 35mm pre-cut stoma hole	31066
XPCCL538	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 38mm pre-cut stoma hole	31066
XPCCL543	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 43mm pre-cut stoma hole	31066
XPCCL713	Flair Active® Curvex	Ostomy device one-piece, closed, large plateau (43mm), 13mm starter hole	31066
Flair Active® Curvex, Ostomy Device One-Piece, Drainable			
XPCDS513	Flair Active® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 13mm starter hole	31075
XPCDS519	Flair Active® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 19mm pre-cut stoma hole	31075
XPCDS522	Flair Active® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 22mm pre-cut stoma hole	31075
XPCDS713	Flair Active® Curvex	Ostomy device one-piece, drainable, small plateau (25mm), 13mm starter hole	31075
XPCDM513	Flair Active® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 13mm starter hole	31075
XPCDM525	Flair Active® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 25mm pre-cut stoma hole	31075
XPCDM529	Flair Active® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 29mm pre-cut stoma hole	31075
XPCDM532	Flair Active® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 32mm pre-cut stoma hole	31075
XPCDM713	Flair Active® Curvex	Ostomy device one-piece, drainable, medium plateau (32mm), 13mm starter hole	31075
XPCDL513	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 13mm starter hole	31075
XPCDL532	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 32mm pre-cut stoma hole	31075
XPCDL535	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 35mm pre-cut stoma hole	31075
XPCDL538	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 38mm pre-cut stoma hole	31075
XPCDL543	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 43mm pre-cut stoma hole	31075
XPCDL713	Flair Active® Curvex	Ostomy device one-piece, drainable, large plateau (43mm), 13mm starter hole	31075
Flair Active® Curvex, Ostomy Device One-Piece, Urostomy			
XPCUS513	Flair Active® Curvex	Ostomy device one-piece, urostomy, small plateau (25mm), 13mm starter hole	64583
XPCUS519	Flair Active® Curvex	Ostomy device one-piece, urostomy, small plateau (25mm), 19mm pre-cut stoma hole	64583
XPCUS522	Flair Active® Curvex	Ostomy device one-piece, urostomy, small plateau (25mm), 22mm pre-cut stoma hole	64583

XPCUS525	Flair Active® Curvex	Ostomy device one-piece, urostomy, small plateau (25mm), 25mm pre-cut stoma hole	64583
XPCUS713	Flair Active® Curvex	Ostomy device one-piece, urostomy, small plateau (25mm), 13mm starter hole	64583
XPCUM513	Flair Active® Curvex	Ostomy device one-piece, urostomy, medium plateau (35mm), 13mm starter hole	64583
XPCUM525	Flair Active® Curvex	Ostomy device one-piece, urostomy, medium plateau (35mm), 25mm pre-cut stoma hole	64583
XPCUM529	Flair Active® Curvex	Ostomy device one-piece, urostomy, medium plateau (35mm), 29mm pre-cut stoma hole	64583
XPCUM532	Flair Active® Curvex	Ostomy device one-piece, urostomy, medium plateau (35mm), 32mm pre-cut stoma hole	64583
XPCUM713	Flair Active® Curvex	Ostomy device one-piece, urostomy, medium plateau (35mm), 13mm starter hole	64583
XPCUL513	Flair Active® Curvex	Ostomy device one-piece, urostomy, large plateau (43mm), 13mm starter hole	64583
XPCUL532	Flair Active® Curvex	Ostomy device one-piece, urostomy, large plateau (43mm), 32mm pre-cut stoma hole	64583
XPCUL538	Flair Active® Curvex	Ostomy device one-piece, urostomy, large plateau (43mm), 38mm pre-cut stoma hole	64583
XPCUL713	Flair Active® Curvex	Ostomy device one-piece, urostomy, large plateau (43mm), 13mm starter hole	64583

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	Updated with EU Authorised Representative details
3.0	Beata Lesiak	01/06/2021	Transition to Medical Device Regulation EU/2017/745

