Ostoform Declaration of Conformity

Name & Address of the Manufacturer:	Ostoform Ltd Unit 5C, Fairgreen House, St Loman's Terrace Mullingar, Co. Westmeath, N91H635 Ireland
Single Registration Number (SRN):	IE-MF-000014357
Notified Body:	National Standards Authority of Ireland, No. 1 Swift Square, Northwood, Santry, Dublin 9, D09 A0E4 Ireland
Notified Body Identification Number:	0050
Competent Authority:	The Health Products Regulatory Authority, Block A, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77 Ireland
Name of Devices:	**Ostoform Crest Moldable Barrier**
Product Codes:	See Annex 1 attached.
Intended Use:	Non-sterile, single-use Medical Device that acts as: Skin protection from stoma output (ostomy or fistula). An external packing agent on uneven peristomal skin. An extension for the FLOWASSIST Seal (Seal) up to 2 ¼" (55mm).
Reference No.:	See Annex 1
Basic UDI-DI:	539153622OFAKP
EMDN Code:	A108001, (Rings/Bezels/Plates for Peristomal Skin)

Device Classification: Class I, Non-sterile medical device in accordance with EU MDR 2017/745 Annex VIII Rules 1 and 4.

Conformity Assessment: Ostoform applies the standards required for CE Labelling of their products according to Regulation MDR 2017/745

This declaration of conformity is issued under the sole responsibility of Ostoform Ltd.
We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.
This declaration is supported by the Quality System approval to ISO 13485:2016 issued by NSAI.
Common specifications are not applicable to this device.
All supporting documentation is retained at the premises of the legal manufacturer.

Signed on Behalf of Ostoform Ltd:  **Date: 1st Oct 2024**

Jean Fuery- Quality Manager
PRRC(Person Responsible for Regulatory Compliance)

Place of signature: Mullingar, Co. Westmeath, Ireland
Issue # 1

Annex I:

Name of Device	Product Code	UDI-DI
Ostoform Crest Moldable Barrier	A1-BSFMz	05391536221287