



MANUFACTURER'S DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Medical Device Regulation (MDR) 2017/745 relating to Eakin Cohesive seals and skin barriers. This declaration is issued under the sole responsibility of TG Eakin Ltd.

Manufacturer's Name: TG Eakin Ltd

Business Address: 15 Ballystockart Road, Comber, Co. Down,
BT23 5QY, Northern Ireland

Medical Device(s): See attached list

Risk Class: Class I in accordance with MDR Annex VIII

Basic UDI-DI (GMN): 050562768COHSEALS1TO6PC

Statement of Compliance: I hereby confirm that the device(s) covered by this declaration are in conformity with the stated regulation.

Scope of Application: This certificate is valid for all products identified in the attached list for an undetermined period of time.

Common specifications used: None

Single Registration number (SRN): XI-MF-000006712

Authorised Signatory:

A handwritten signature in black ink, appearing to read "Janet Fairlie-Vogt", written over a horizontal line.

Janet Fairlie-Vogt
Interim Director, International Ostomy & Wound
For and on behalf of TG Eakin Limited
Date of issue: 08 JUN 2021
Place of issue: Comber, Co. Down

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Controlled Listings for CE - Marked Products (Eakin Cohesive seals and skin barriers)

Declaration of Conformity: TGE001

Product Reference No.	Product description	UDI-DI
839001	Large Cohesive Seal	5060267410009
839002	Small Cohesive Seal	5060267410016
839003	Large Cohesive Skin Barrier	5060267410023
839004	Small Cohesive Skin Barrier	5060267410030
839005	Cohesive Slims	5060267410047
839006	Cohesive StomaWrap	5060267413802
NL839002	Small Cohesive Seals - Netherlands	5060267414106
NL839005	Cohesive Slims - Netherlands	5060267414113
PHC839001	Cohesive Seals - Large	5060267410825
PHC839002	Cohesive Seals - Small	5060267410832
PHC839005	Cohesive Seals - Slims	5060267410849
PHC839006	Stoma Wrap	5060267414137
SE839001	Large Cohesive Seal - Sweden	5060267413178
SE839002	Small Cohesive Seal - Sweden	5060267413185
SE839003	Cohesive Barriers - Large	5060267414779
SE839004	Cohesive Barriers - Small	5060267414786
SE839005	Cohesive Slims – Sweden	5060267413192
DE839001	Large Cohesive Seals – Germany	5060267410740
DE839002	Small Cohesive Seals - Germany	5060267410757
DE839003	Cohesive Barriers - Large	5060267415752
DE839004	Cohesive Barriers - Small	5060267415769
DE839005	Slims 10 pack for Germany	5060267413482
DE839006	Stoma Wrap – Germany	5060267414199
839001	Large Cohesive Seals Japan	4573296400015
839002	Small Cohesive Seals Japan	4573296400022
839003	Large Cohesive Skin Barriers Japan	4573296400039
839004	Small Cohesive Skin Barriers Japan	4573296400046
839005	Cohesive Slims Japan	4573296400053
839006	Cohesive StomaWrap Japan	4573296400060
839001	839001 France	5056276806247
839002	839002 France	5056276806254
839005	839005 France	5056276806261
839006	839006 France	5056276806278

And any of the above product codes prefixed by SP which denotes a sample of the same item.