eakin®

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 Limited.

Manufacturer's Name:	TG Eakin Limited
Business Address:	15 Ballystockart Road, Co. Down, BT23 5QY, Northern Ireland, U.K.
Medical Device(s):	See attached list
Risk Class:	Class I in accordance with MDR Annex VIII
Intended Purpose:	Skin protecting seals / skin barriers / ostomy seals
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:

Grace Mc Groggan

Grace McGroggan, Head of Clinical and Regulatory Affairs
For and on behalf of TG Eakin Limited
Date of issue: 18TH AUGUST 2022
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
839001	Large Cohesive Seal
839002	Small Cohesive Seal
839003	Large Cohesive Skin Barrier
839004	Small Cohesive Skin Barrier
839005	Cohesive Slims
839006	Cohesive StomaWrap
NL839002	Small Cohesive Seals - Netherlands
NL839005	Cohesive Slims - Netherlands
PHC839001	Cohesive Seals - Large
PHC839002	Cohesive Seals - Small
PHC839005	Cohesive Seals - Slims
PHC839006	Cohesive StomaWrap
SE839001	Large Cohesive Seal - Sweden
SE839002	Small Cohesive Seal - Sweden
SE839003	Cohesive Barriers - Large
SE839004	Cohesive Barriers - Small
SE839005	Cohesive Slims – Sweden
DE839001	Large Cohesive Seals – Germany
DE839002	Small Cohesive Seals - Germany
DE839003	Cohesive Barriers - Large
DE839004	Cohesive Barriers - Small
DE839005	Cohesive Slims 10 pack for Germany
DE839006	Cohesive StomaWrap – Germany
839001	Large Cohesive Seals Japan
839002	Small Cohesive Seals Japan
839003	Large Cohesive Skin Barriers Japan
839004	Small Cohesive Skin Barriers Japan
839005	Cohesive Slims Japan
839006	Cohesive StomaWrap Japan
839001FR	Large Cohesive Seal France
839002FR	Small Cohesive Seal France
839005FR	Cohesive Slims France
839006FR	Cohesive StomaWrap France
And any of the above product codes prefixed or suffixed by a 2-letter country code (e.g. FR, DE, JP) which denotes a country-specific variant of the same item, which is identical to the item listed above, differing in labelling language, UDI and/or pack size only	