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 paste. 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 protector around wounds, stomas and fistulae
Basic UDI-DI (GMN):	050562768COHPASTEUG
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 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 ostomy paste)
Declaration of Conformity: TGE007

Product Reference No.	Product description
839010	Eakin Cohesive paste 60g
SP839010	Eakin Cohesive paste 20g
And any of the above product codes prefixed by a 2-letter country code (e.g. DE, JP, FR) 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	