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 Release adhesive remover. 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-D (GMN)I:	050562768RELEASEHR
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:

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 Release adhesive remover)

Declaration of Conformity: TGE010

Product Reference No.	Product description	UDI-DI
839023	Eakin Release aerosol 50ml	5060267410108
839024	Eakin Release wipes (box of 30)	5060267410115
And any of the above product codes prefixed by SP which denotes a sample of the same item, or 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		