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 Limited.

| | |
|---|---|
| ***Manufacturer's Name:*** | TG Eakin Limited |
| ***Business Address:*** | 15 Ballystockart Road, Co. Down,<br>BT23 5QY, Northern Ireland, U.K. |
| ***Medical Device(s):*** | See attached list |
| ***Risk Class:*** | Class I in accordance with MDR Annex VIII |
| ***Intended Purpose:*** | Adhesive remover for medical adhesives |
| ***Basic UDI-DI (GMN):*** | 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:***

Grace Mc Groggan

Grace McGroggan, Head of Clinical and Regulatory Affairs
For and on behalf of TG Eakin Limited
Date of issue: 8TH AUGUST 2022
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 |
|---|---|
| 839023 | Eakin Release aerosol 50ml |
| 839024 | Eakin Release wipes (box of 30) |
| 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 | |