



## 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 Wound pouches. 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):** 050562768WOUNDPOUCHES2S


**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:**

 24-NOV-2021

Janet Fairlie-Vogt  
Interim Director, International Ostomy & Wound  
For and on behalf of TG Eakin Limited  
Date of issue: 24 - NOV - 2021  
Place of issue: Comber, Co. Down

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## Controlled Listings for CE - Marked Products (Eakin Wound pouches)

### Declaration of Conformity: TGE002

Product Reference No.	Product description
839250	Wound Pouch S
839251	Wound Pouch M
839252	Wound Pouch L
839253	Wound Pouch XL
839260	Wound Pouch with bung S
839261	Wound Pouch with bung M
839262	Wound Pouch with bung L
839263	Wound Pouch with bung XL
839264	Wound Pouch with bung & window XL
839265	Wound Pouch with bung (vertical) XL
839266	Wound Pouch with bung XXL
839267	Wound Pouch with bung S+ (86mm x 60mm)
839268	Wound Pouch with bung & window (vertical) XL
839269	Maxi Wound Pouch
839270	Wound Pouch Midline
839280	Access Window for wound pouch
839281	Small Access Window for wound pouch
SE839250	Wound Pouch - S
SE839251	Wound Pouch - M
SE839252	Wound Pouch - L
SE839253	Wound Pouch - XL
SE839260	Wound Pouch with bung - S
SE839261	Wound Pouch with bung - M
SE839262	Wound Pouch with bung - L
SE839263	Wound Pouch with bung - XL
SE839264	Wound Pouch with bung & win - XL
SE839265	Wound Pouch with bung (V) - XL
SE839266	Wound Pouch with bung - XXL
SE839267	Wound Pouch S+
SE839268	Wound Pouch with bung (V) & win XL
SE839269	Maxi Wound Pouch 250 x 385mm
SE839270	Midline Wound Pouch with bung
SE839280	Access Window for wound pouch
DE839250	Wound Pouch - S
DE839251	Wound Pouch - M
DE839252	Wound Pouch - L
DE839253	Wound Pouch - XL
DE839260	Wound Pouch with Bung - S
DE839261	Wound Pouch with Bung - M
DE839262	Wound Pouch with Bung - L



DE839263	Wound Pouch with Bung - XL
DE839264	Wound Pouch with Bung & Window - XL
DE839265	Wound Pouch with Bung (V) - XL
DE839266	Wound Pouch with Bung - XXL
DE839267	Wound Pouch - S+
DE839268	Wound Pouch with Bung (V) & Window - XL
DE839269	Maxi Wound Pouch
DE839270	Midline Wound Pouch with Bung - Germany
DE839280	Access Window for wound pouch
DE839281	Small Access Window for wound pouch - Germany