



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 Dot 2-piece ostomy appliances. 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: See attached list

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

Authorised Signatory:

Janet Fairlie-Vogt
Interim Director, International Ostomy & Wound
For and on behalf of TG Eakin Limited
Date of issue: 14th May 2021
Place of issue: Comber, Co. Down

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Controlled Listings for CE - Marked Products (Eakin Dot 2-piece ostomy appliances)

Declaration of Conformity: TGE003

Product Reference No.	Product description	Basic UDI-DI
839800	Eakin dot 2 Piece 60mm Flat Base Plate CTF 15-37.5mm	5060267414953
839801	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 20mm	5060267414960
839802	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 22.5mm	5060267414977
839803	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 25mm	5060267414984
839804	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 27.5mm	5060267414991
839805	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 30mm	5060267415004
839806	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 32.5mm	5060267415011
839807	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 35mm	5060267415028
839808	Eakin dot 2 Piece 60mm Flat Base Plate Pre-cut 37.5mm	5060267415035
839809	Eakin dot 2 Piece 80mm Flat Base Plate CTF 15-50mm	5060267415042
839810	Eakin dot 2 Piece 80mm Flat Base Plate Pre-cut 40mm	5060267417206
839811	Eakin dot 2 Piece 80mm Flat Base Plate Pre-cut 45mm	5060267417213
839812	Eakin dot 2 Piece 80mm Flat Base Plate Pre-cut 50mm	5060267417220
839820	eakin dot 2 Piece 60mm Convex base plate CTF 15-40mm	5056276801365
839821	eakin dot 2 Piece 60mm Convex base plate Pre-cut 20mm	5056276801372
839822	eakin dot 2 Piece 60mm Convex base plate Pre-cut 22.5mm	5056276801389
839823	eakin dot 2 Piece 60mm Convex base plate Pre-cut 25mm	5056276801396
839824	eakin dot 2 Piece 60mm Convex base plate Pre-cut 27.5mm	5056276801402
839825	eakin dot 2 Piece 60mm Convex base plate Pre-cut 30mm	5056276801419
839826	eakin dot 2 Piece 60mm Convex base plate Pre-cut 32.5mm	5056276801426



839827	eakin dot 2 Piece 60mm Convex base plate Pre-cut 35mm	5056276801433
839828	eakin dot 2 Piece 60mm Convex base plate Pre-cut 37.5mm	5056276801440
839829	eakin dot 2 Piece 60mm Convex base plate Pre-cut 40mm	5056276801457
839830	eakin dot 2 Piece 80mm Convex base plate CTF 15-60mm	5056276801464
839900	Eakin dot 2 Piece 60mm Closed Mini Clear Pouch	5060267415059
839901	Eakin dot 2 Piece 60mm Closed Standard Clear Pouch	5060267415066
839902	Eakin dot 2 Piece 60mm Closed Maxi Clear Pouch	5060267415073
839903	Eakin dot 2 Piece 60mm Drainable Mini Clear Pouch	5060267415080
839904	Eakin dot 2 Piece 60mm Drainable Standard Clear Pouch	5060267415097
839905	Eakin dot 2 Piece 60mm Drainable Maxi Clear Pouch	5060267415103
839920	Eakin dot 2 Piece 80mm Closed Standard Clear Pouch	5060267417237
839921	Eakin dot 2 Piece 80mm Closed Maxi Clear Pouch	5060267417244
839922	Eakin dot 2 Piece 80mm Drainable Standard Clear Pouch	5060267417251
839923	Eakin dot 2 Piece 80mm Drainable Maxi Clear Pouch	5060267417268
And any of the above product codes prefixed by SP which denotes a sample of the same item.		