

EU DECLARATION OF CONFORMITY

Essity Hygiene and Health AB SE-405 03 Göteborg Sweden Visitor's address: Mölndals Bro 2, Mölndal

SRN number: SE-MF-00000004

hereby declares being the manufacturer* of the medical devices TENA Rectangular Pads according to the enclosed article number list, and that the devices are in conformity with Medical Device Regulation (EU) 2017/745 (MDR) and fulfil all relevant requirements in MDR.

The devices are intended for incontinence care and are classified in Class I according to Annex VIII in MDR.

The GMDN code is 35817, the EMDN/CND code is T04010101 and the Basic UDI-DI is 7322540100746X.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Article Number	Article	UDI-DI
1100	TENA Rect Pad with PE backsheet 6x30 pcs	7310791055893
1102	TENA Rect Pad with NW backsheet 6x30 pcs	7310791198835
1165	TENA Rectangular pad 6x30p	7322540726626
750640	TENA Maxi Diaper with fix pant 2x40pcs	7310797506405
753900	TENA Maxi Diaper with NW backsheet 4x40p	7310791055947

Mölndal, on January 2021-01-26

Romana Stefek Global Regulatory Affairs/Product Safety Director LM Essity Hygiene and Health AB

* per definition in Medical Device Regulation (EU) 2017/745

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This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB SE-405 03 GÖTEBORG Sweden

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Document Name		
Declaration of Conformity	FORM-00733	4.0