

EU DECLARATION OF CONFORMITY

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

SRN number: SE-MF-000000004

Product assortment: TENA Rectangular Pads

Basic UDI-DI: 7322540100746X

Medical devices: See enclosed list

Risk class: Class I

Common Specification: N/A

Notified Body: N/A, since class I device

Declaration: We hereby declare being the manufacturer* of the medical devices 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 safety and functional requirements in MDR.

The devices are classified in according to Annex VIII in MDR. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Intended use: The devices are intended for incontinence care

GMDN code: 35817

EMDN code: T04010101

Signatory: Mölndal, on 2022-04-07



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

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

This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

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Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	6.0

Article number	Article Name	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

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