

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-000000004

hereby declares being the manufacturer* of the medical devices TENA Pants Bariatric 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 41588, the EMDN/CND code is T04010103 and the Basic UDI-DI is 73225401008473.

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

Article number	UDI-DI number	Article
792862	7322541263007	TENA Pants Bariatric Plus XXL, 4x12 pcs
100342	7322540901108	TENA Pants Bariatric Plus XXL, 36x1, AB

Mölndal, on January 2021-01-22



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 Romana Stefek
 Global Regulatory Affairs/Product Safety Director
 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
Declaration of Conformity	FORM-00733