

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 Pants Bariatric

Basic UDI-DI: 73225401008473

Medical devices: See enclosed article number list

Risk class: Class I
The devices are classified according to Annex VIII of EU MDR

Common Specification: N/A

Notified Body: N/A since class I device

Declaration: We, Essity Hygiene and Health AB, declare under sole responsibility as manufacturer that the medical devices enclosed in the article number list, are in conformity with Medical Device Regulation (EU) 2017/745 (MDR) and fulfil all relevant safety and functional requirements in EU MDR.

Intended purpose: The main intended use of the product is that:
1. it shall absorb urine from incontinent individuals
2. it shall keep the skin dry
3. it shall temporarily capture faeces

GMDN code: 11239

EMDN code: T04010103

Signatory: Mölndal, on Oct 24, 2024



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

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This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	7.0

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

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	7.0