

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 Stretch

Basic UDI-DI: 7322540100716R

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 temporarily capture faeces
 3. it shall keep the skin dry

GMDN code: 11239

EMDN code: T04010103

Signatory: Mölndal, on 2025-12-16



Romana Stefek
 Global Regulatory Affairs Director
 PRRC Medical Devices, Cosmetics/Biocides, Certified Products

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This declaration is valid until a new version is issued, but not longer than November 26th, 2026.

Seat: Göteborgs kommun. Registration number: SE556007-2356

Document Name	Document ID	Version
Declaration of Conformity	FORM-000733	7.0

TENA Stretch Articles:

Article number	Article Name	CON UDI-DI
761194	TENA Stretch Night Super, M 2x30p INT/NEU	7322542291078
761196	TENA Stretch Night Super, L 2x30p INT/NEU	7322542291306
761197	TENA Stretch Day Super, M 2x30p INT/NEU	7322542291412
761198	TENA Stretch Day Super L 2x30p INT/NEU	7322542291542
761199	TENA Stretch Night Super, M 4x10p INT/NEU	7322542291658
761204	TENA Stretch Night Super, L 4x10p INT/NEU	7322542291788
761205	TENA Stretch Day Super, M 4x10p INT/NEU	7322542291863
761206	TENA Stretch Day Super, L 4x10p INT/NEU	7322542291993

TENA Stretch Sample Articles:

Article number	Article Name	CON UDI-DI
101274	TENA Stretch Day Super L Ps 60x1p West	7322542489383
101275	TENA Stretch Night Super, M Ps 60x1p West	7322542489437
101276	TENA Stretch Night Super, L Ps 60x1p West	7322542489475
101277	TENA Stretch Day Super, M Ps 60x1p East	7322542489529
101278	TENA Stretch Day Super L Ps 60x1p East	7322542489567
101279	TENA Stretch Night Super, M Ps 60x1p East	7322542489611
101280	TENA Stretch Night Super, L Ps 60x1p East	7322542489659
101282	TENA Stretch Day Super, M Ps 60x1p West	7322542489345

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EU Declaration of Conformity TENA Stretch - 2025-12

Final Audit Report

2025-12-16

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