

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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