

UK 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 Men

Basic UDI-DI: 73225401009373

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 UK Medical Device Regulation 2002 No.618 (UK MDR) and fulfil all relevant requirements in UK MDR.

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

The Authorized Representative in UK is

Essity UK Ltd
Southfields Road
DUNSTABLE
Bedfordshire
LU6 3EJ

Intended use: The devices are intended for incontinence care

GMDN code: 11239

EMDN code: T04010102

Signatory: Mölndal, on Mar 26, 2024



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.

Essity Hygiene and Health AB
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Dokument namn	Dokument ID	Version	Gäller från
UK Declaration of Conformity	FORM-36124	3.0	2022-04-04

Article number	Article name	UDI-DI
750404	TENA Men Active Fit Shield, 3x14p, SRP	7322540770339
750463	TENA Men Active Fit Shield, 8x14p SRU eC	7322540893632
750651	TENA Men Active Fit L1, 6x24p, Int	7322540426359
750658	TENA Men Active Fit L1, 4x12p, SRP	7322540426335
750661	TENA Men Active Fit L1, 8x12p, Int	7322540426335
750676	TENA Men Active Fit L1, 8x12p, SRU eC	7322540893656
750776	TENA Men Active Fit L2, 6x20p, Int	7322540016383
750797	TENA Men Active Fit L2, 3x10p, SRP	7322540016413
750809	TENA Men Active Fit L2, 6x10p, SRU eC	7322540893724
750830	TENA Men Active Fit L3, 6x16p, Int	7322540463620
750856	TENA Men Active Fit L3, 6x8p, Int	7322540560602
750900	TENA Men Active Fit L3, 6x8p, SRU eC	7322542307168

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UK Declaration of Conformity	FORM-36124	3.0	2022-04-04