

# 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 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 Medical Device Regulation (EU) 2017/745 (MDR) and fulfil all relevant safety and functional requirements in MDR.

The devices are classified in according to Annex VIII in MDR. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

**Intended use:** The devices are intended for incontinence care

**GMDN code:** 11239

**EMDN code:** T04010102

**Signatory:** Mölndal, on Apr 25, 2024



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

\* 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	Version
Declaration of Conformity	FORM-00733	6.0

Article number	Article	UDI-DI number
50751	TENA Men Absorbent Guards, 6x20p, MX	7322540259711
100016	TENA Men Active Fit L2, 120x1 A	7322541240398
100017	TENA Men Active Fit L3, 64x1 A	7322541240978
100027	TENA Men Active Fit L0, 252x1 A	7322541242248
100028	TENA Men Active Fit L0, 252x1p B	7322541242361
100029	TENA Men Active Fit L1, 144x1 A	7322541242491
100031	TENA Men Active Fit L1, 144x1 B	7322541242620
100032	TENA Men Active Fit L2, 120x1 B	7322541242736
100033	TENA Men Active Fit L3, 64x1 B	7322541242880
100255	TENA Men Protective Shield Level 0, 130x1 C	7322541256566
100256	TENA Men Light Level 1 70x1 C	7322541256696
100257	TENA Men Medium Level 2 112x1 C	7322541269719
100258	TENA Men Super Level 3 80x1 C	7322541256931
100511	TENA Men Active Fit L0, 130x1 CD mix	7322541345864
100512	TENA Men Active Fit L1, 70x1 CD mix	7322541345888
100513	TENA Men Active Fit L2, 112x1 CD mix	7322541345901
100514	TENA Men Active Fit L3, 80x1 CD mix	7322541345925
100659	TENA Men Level 1, 144x1 A	7322541874036
100660	TENA Men Level 1, 70x1 CD mix	7322541874111
100661	TENA Men Level 2, 120x1 A	7322541874203
100662	TENA Men Level 2, 112x1 CD mix	7322541874289
100663	TENA Men Level 3, 64x1 A	7322541874371
100664	TENA Men Level 3, 80x1 CD mix	7322541874456
750403	TENA Men Protective Shield Extra Light, 8x14p	7322540770339
750404	TENA Men Active Fit Shield, 3x14p, SRP	7322540770339
750406	TENA Men Active Fit Shield, 8x14p FR/IT	7322540770377
750449	TENA Men Protective Shield Extra Light, 8x14p	7322540770339
750459	TENA Men Protective Shield, Level 0, 8x14p, East	7322540869927
750463	TENA Men Active Fit Shield, 8x14p SRU eC	7322540893632
750535	TENA Men Active Fit Shield, 8x14p Neu	7322541495309
750536	TENA Men Active Fit Shield, 3x14p DE SRP	7322541691770
750651	TENA Men Active Fit L1, 6x24p, Int	7322540426359
750652	TENA Men Active Fit L1, 6x24p, FR	7322540426397
750653	TENA Men Active Fit L1, 6x24p, IT	7322540426410
750654	TENA Men Level 1 Light, 6x24p	7322540426359
750658	TENA Men Active Fit L1, 4x12p, SRP	7322540426335
750661	TENA Men Active Fit L1, 8x12p, Int	7322540426335
750662	TENA Men Level 1 Light, 8x12p	7322540426373
750663	TENA Men Active Fit L1, 8x12p, FR	7322540426311
750676	TENA Men Active Fit L1, 8x12p, SRU eC	7322540893656

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	6.0

750677	TENA Men Active Fit L1, 6x24p, ES, PT	7322540934519
750682	TENA Men Active Fit L1, 8x12p RTeC Neu	7322541314174
750683	TENA Men Active Fit L1, 6x24p, East	7322541493053
750684	TENA Men Active Fit L1, 6x24p, Neu SWAN	7322541493121
750701	TENA Men Active Fit L1, 8x12p, DE	7322541497341
750703	TENA Men Level 1, 6x24p	7322541500898
750704	TENA Men Level 1, 8x12p	7322541501024
750706	TENA Men Level 2, 6x20p	7322541501154
750708	TENA Men Level 3, 6x16p	7322541501468
750710	TENA Men Active Fit L1, 6x24p, IT, NEU	7322540426410
750711	TENA MEN Active Fit L2, 6x20p, IT, NEU	7322540426502
750713	TENA Men Active Fit L3, 6x16p, IT, NEU	7322540467048
750715	TENA Men Active Fit L1, 8x14p, DE Promo	7322542420195
750759	TENA Men Active Fit L2, 4x10p, SRP	7322540016413
750776	TENA Men Active Fit L2, 6x20p, Int	7322540016383
750784	TENA Men Level 2 Medium, 6x20p	7322540016383
750789	TENA Men Active Fit L2, 6x20p, FR	7322540426489
750795	TENA Men Active Fit L2, 6x20p, IT	7322540426502
750796	TENA Men Active Fit L2, 6x10p, Int	7322540016413
750797	TENA Men Active Fit L2, 3x10p, SRP	7322540016413
750798	TENA Men Active Fit L2, 6x10p, DE	7322540770179
750809	TENA Men Active Fit L2, 6x10p, SRU eC	7322540893724
750829	TENA Men Active Fit L2, 6x20p, ES, PT	7322540934571
750830	TENA Men Active Fit L3, 6x16p, Int	7322540463620
750833	TENA Men Level 3 Super, 6x16p	7322540463620
750834	TENA Men Active Fit L3, 6x16p, FR	7322540467048
750835	TENA Men Active Fit L3, 6x16p, IT	7322540467048
750855	TENA Men Level 3 Super, 6x8p	7322540769975
750856	TENA Men Active Fit L3, 6x8p, Int	7322540560602
750858	TENA Men Active Fit L3, 6x20p, East	7322540792065
750860	TENA Men Active Fit L3, 6x16p, ES, PT	7322540935684
750863	TENA Men Active Fit L3, 6x8p, FR	7322540969573
750865	TENA Men Active Fit L2, 8x10p, FR	7322540426465
750868	TENA Men Active Fit L2, 6x10p RTeC NEU	7322541314297
750873	TENA Men Active Fit L2, 6x20p East	7322541493237
750874	TENA Men Active Fit L2, 6x20p, Neu SWAN	7322541493329
750876	TENA Men Active Fit L3, 6x16p, Neu SWAN	7322541493497
750878	TENA Men Active Fit L2, 6x10p, DE	7322541497426
750879	TENA Men Active Fit L3, 6x8p, DE	7322541497501
750899	TENA MEN Active Fit L2, 6x12p, DE Promo	7322542035658
750900	TENA Men Active Fit L3, 6x8p, SRU eC	7322542307168

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## PROHLÁŠENÍ O SHODĚ ES

**Společnost:** Essity Hygiene and Health AB  
SE-405 03 Göteborg  
Sweden  
Adresa: Mölndals Bro 2, Mölndal, Sweden  
  
SRN number: SE-MF-000000004

**Produkty:** TENA Men

**Basic UDI-DI:** 73225401009373

**Zdravotnický prostředek:** Seznam níže  
**Riziková třída:** Třída I

**Specifikace:** N/A

**Notifikovaná osoba:** N/A, riziková třída I

**Prohlášení:** tímto prohlašujeme jako výrobce\* zdravotnických prostředků uvedených v seznamu níže, že zdravotnické prostředky splňují příslušná ustanovení Nařízení o zdravotnických prostředcích (EU) 2017/745 (MDR) a splňují veškeré relevantní požadavky na bezpečnost a funkčnost stanovené MDR. Prostředky jsou klasifikované dle přílohy VIII MDR. Toto prohlášení o shodě je vydáno dle výhradní zodpovědnosti výrobce.

**Účel použití:** Prostředky jsou určeny pro inkontinenční péči.  
**GMDN kód:** 11239  
**EMDN kód:** T04010102

### Signatory:

Mölndal, dne 25.4.2024  
Romana Stefek  
Global Regulatory Affairs/Product Safety Director  
PRRC, LM Essity Hygiene and Health AB  
*\* dle definice v nařízení o zdravotnických prostředcích (EU) 2017/745*

Toto prohlášení zůstává v platnosti, dokud není nahrazeno novou verzí.

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