EU DECLARATION OF CONFORMITY

Essity Hygiene and Health AB
SE-405 03 Göteborg
Sweden
Visitor's address: Mölndals Bro 2, Mölndal

SRN number: SE-MF-000000004

hereby declares being the manufacturer* of the medical devices TENA Men 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 requirements in MDR.

The devices are intended for incontinence care and are classified in Class I according to Annex VIII in MDR.

The GMDN code is 11239, the EMDN/CND code is T04010102 and the Basic UDI-DI is 73225401009373.

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

** per definition in Medical Device Regulation (EU) 2017/745*

Mölndal, on 2021-01-27

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Romana Stefek
Global Regulatory Affairs/Product Safety Director
LM Essity Hygiene and Health AB

This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB
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Sweden
Visitors' address:Mölndals Bro 2, Mölndal
Phone: +46 31 746 00 00
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Article number	Article	UDI-DI number
50600	TENA Men, level 2	768702506007
50701	TENA Men Prot Guards Level 2 6x10p	768702507011
50730	TENA Men Absorbent Shields, 8x14p, CA	768702507301
50751	TENA Men Absorbent Guards, 6x20p, MX	7322540259711
52700	TENA Men Absorbent Guards, 3x48p, CA	380040527003
54196	TENA Men Absorbent Guards, 3x20p, US	768702541961
54197	TENA Men Absorbent Guards, 3x48p,US	768702527002
54304	TENA MEN Super Guard 6x16 NA	768702543040
54311	TENA MEN Guard Moderate 3x48 ECOM	768702543118
54314	TENA MEN Super Guard 6x16 ECOM	768702543149
100016	TENA Men Medium Level 2, 120x1 A	7322541240398
100017	TENA Men Super Level 3, 64x1 A	7322541240978
100027	TENA Men Protective Shield Level 0, 252x1 A	7322541242248
100028	TENA Men Protective Shield Level 0, 252x1 B	7322541242361
100029	TENA Men Light Level 1, 144x1 A	7322541242491
100031	TENA Men Light Level 1, 144x1 B	7322541242620
100032	TENA Men Medium Level 2, 120x1 B	7322541242736
100033	TENA Men Super Level 3m, 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 Prot Shield Lev 0, 130x1 CD mix	7322541345864
100512	TENA Men Light Level 1, 70x1 CD mix	7322541345888
100513	TENA Men Medium Level 2, 112x1 CD mix	7322541345901
100514	TENA Men Super Level 3, 80x1 CD mix	7322541345925
750403	TENA Men Protective Shield Extra Light, 8x14p	7322540770339
750404	TENA Men Protective Shield, 3x14p	7322540770339
750406	TENA Men Protective Shield, 8x14p	7322540770377
750449	TENA Men Protective Shield Extra Light, 8x14p	7322540770339
750459	TENA Men Protective Shield, Level 0, 8x14p, East	7322540869927
750463	TENA Men Protective Shield, Level 0, 8x14p, eC	7322540893632
750651	TENA Men Level 1 Light, 6x24p	7322540426359
750652	TENA Men Level 1 Light, 6x24p	7322540426397
750653	TENA Men Level 1 Light, 6x24p	7322540426410
750654	TENA Men Level 1 Light, 6x24p	7322540426359
750658	TENA Men Level 1 Light, 4x12p	7322540426335
750661	TENA Men Level 1 Light, 8x12p	7322540426335
750662	TENA Men Level 1 Light, 8x12p	7322540426373

750663	TENA Men Level 1 Light, 8x12p	7322540426311
750676	TENA Men Light Level 1, 8x12p, SRU eC	7322540893656
750677	TENA MEN Light Level 1, 6x24p, ES/PT	7322540934519
750682	TENA Men Light Level 1, 8x12p, RTeC NEU	7322541314174
750700	TENA MEN Medium Level 2, 2x10p, SRP	7322540016413
750759	TENA Men Level 2 Medium, 4x10p	7322540016413
750776	TENA Men Level 2 Medium, 6x20p	7322540016383
750784	TENA Men Level 2 Medium, 6x20p	7322540016383
750789	TENA Men Level 2 Medium, 6x20p	7322540426489
750795	TENA Men Level 2 Medium, 6x20p	7322540426502
750796	TENA Men Level 2 Medium, 6x10p	7322540016413
750797	TENA Men Level 2 Medium, 3x10p	7322540016413
750798	TENA Men Level 2 Medium, 6x10p	7322540770179
750800	TENA Men Level 2 Medium, 6x10p	7322540426465
750809	TENA MEN Medium Level 2, 6x10p, eC	7322540893724
750829	TENA MEN Medium Level 2, 6x20p, ES/PT	7322540934571
750830	TENA Men Level 3 Super, 6x16p	7322540463620
750833	TENA Men Level 3 Super, 6x16p	7322540463620
750834	TENA Men Level 3 Super, 6x16p	7322540467048
750835	TENA Men Level 3 Super, 6x16p	7322540467048
750836	TENA Men Level 3 Super,3x8p	7322540560602
750855	TENA Men Level 3 Super, 6x8p	7322540769975
750856	TENA Men Level 3 Super, 6x8p	7322540560602
750858	TENA Men Level 3 Super, 6x20p	7322540792065
750860	TENA Men Super Level 3, 6x16p, ES/PT	7322540935684
750863	TENA Men Super Level 3, 6x8p, FR	7322540969573
750865	TENA MEN Medium Level 2, 8x10p, FR	7322540426465
750868	TENA Men Medium Level 2, 6x10p, RTeC NEU	7322541314297

[Logo s textem: essity]

EU PROHLÁŠENÍ O SHODĚ

Společnost
Essity Hygiene and Health AB
SE-405 03 Göteborg
Švédsko
Adresa pro návštěvy: Mölndals Bro 2, Mölndal

Číslo SRN: SE-MF-000000004

tímto prohlašuje, že je výrobcem* zdravotnických prostředků TENA Men Inkontinenční vložky pro muže dle přiloženého seznamu a že tyto prostředky jsou v souladu s nařízením EU č. 2017/745 o zdravotnických prostředcích („nařízení“) a splňují všechny jeho příslušné požadavky.

Prostředky jsou určeny k péči o inkontinentní osoby a jsou klasifikovány jako třída I podle přílohy VIII nařízení.

GMDN kód je 11239, EMDN/CND kód je T04010102 a základní UDI-DI je 73225401009373.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

**podle definice v nařízení (EU) č. 2017/745 o zdravotnických prostředcích*

Mölndal, 27. ledna 2021

[podpis]
……
Romana Stefek

Ředitelka pro globální regulatorní problematiku a bezpečnost výrobků
LM Essity Hygiene and Health AB

Toto prohlášení zůstává v platnosti do vydání nové verze.

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Švédsko

Sídlo: Göteborgs kommun. Reg. číslo: SE556007–2356

Adresa pro návštěvy:
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Tel.: +46 31 746 00 00
www.essity.com

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50751	TENA Men Absorbent Guards, 6x20p, MX	7322540259711
52700	TENA Men Absorbent Guards, 3x48p, CA	380040527003
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100017	TENA Men Super Level 3, 64x1 A	7322541240978
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100029	TENA Men Light Level 1, 144x1 A	7322541242491
100031	TENA Men Light Level 1, 144x1 B	7322541242620
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100033	TENA Men Super Level 3m, 64x1 B	7322541242880
100255	TENA Men Protective Shield Level 0, 130x1 C	7322541256566
100256	TENA Men Light Level 1 70x1 C	7322541256696
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750653	TENA Men Level 1 Light, 6x24p	7322540426410
750654	TENA Men Level 1 Light, 6x24p	7322540426359
750658	TENA Men Level 1 Light, 4x12p	7322540426335
750661	TENA Men Level 1 Light, 8x12p	7322540426335
750662	TENA Men Level 1 Light, 8x12p	7322540426373
750663	TENA Men Level 1 Light, 8x12p	7322540426311

750676	TENA Men Light Level 1, 8x12p, SRU eC	7322540893656
750677	TENA MEN Light Level 1, 6x24p, ES/PT	7322540934519
750682	TENA Men Light Level 1, 8x12p, RTeC NEU	7322541314174
750700	TENA MEN Medium Level 2, 2x10p, SRP	7322540016413
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750860	TENA Men Super Level 3, 6x16p, ES/PT	7322540935684
750863	TENA Men Super Level 3, 6x8p, FR	7322540969573
750865	TENA MEN Medium Level 2, 8x10p, FR	7322540426465
750868	TENA Men Medium Level 2, 6x10p, RTeC NEU	7322541314297