

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 Pants Unisex 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 41588, the EMDN/CND code is T04010103 and the Basic UDI-DI is 73225401008574 and 73225401008472.

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

Mölndal, on March 2021-03-18



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

* 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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Article Number	Name	UDI-DI
100148	TENA Pants Normal L, 56x1, WI, Ps B	7322541245324
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100160	TENA Pants Night Super M, 42x1, WI, Ps, B	7322541246895
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100248	TENA Pants Super XL, 42x1, AB	7322541255767
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100303	TENA Pants Maxi L, 36x1, AB	7322541259437
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100308	TENA Pants Plus Night M, 42x1, A	7322541259918
100311	TENA Pants Plus Night L, 42x1, A	7322541260280
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211264	TENA Pants Plus M, 2x9	7322540592412
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791640	TENA Pants Normal L, 4x10, Rt	7322540762693
791648	TENA Pants Original Normal Large, 4x18, DE	7322540728569
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792330	TENA Pants Super Value M, 4x12, Neu	7322541229973
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792335	TENA Pants Plus Value XL, 4x12, Neu	7322541230023
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792541	TENA Pants Plus M, 2x30p, EAST	7322541063485
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792613	TENA Pants Plus L, 4x14pcs, Sou	7322541063850
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792621	TENA Pants Extra L, 2x30 pcs, EMEA	7322541064017
792624	TENA Pants Plus Classic L, 4x14p, NEU, IT	7322541096216
792625	TENA Pants Plus Large, 4x14p, JP, Ps	7322540574852
792626	TENA Pants Extra, Large 8x10p,NEU,NSW,Ps	7322541355610
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792634	TENA Pants Plus, L, 4x14, IT CODE	7322540893113
792636	TENA Pants Plus L, 4x16	7322540897050
792638	TENA Pants Original Plus L, 4x14p	7322541037134
792645	TENA Pants Plus, L, 4x14, DE	7322540917055
792664	TENA Pants PLUS Large, 4x14, Neutral	7322540574852
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792678	TENA Pants Plus L, 6x8, FR	7322540574876
792679	TENA Pants Plus Large 12x8p, FR	7322540574876
792681	ORLYS Pants Noche G, 8x10p, ES, ProSkin	7322541006734
792682	ORLYS Pants Noche G, 8x10p, ES, ProSkin	7322541217024
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792712	TENA Pants Plus XL, 4x12 pcs	7322540587555
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793521	TENA Pants Super Medium, 4x12p, JP, Ps	7322541140001
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793534	TENA Pants Super, M, 4x12, IT CODE	7322540893038
793538	TENA Pants Super Medium, 4x10p, IT, CODE	7322541181851
793562	TENA Pants SUPER Medium, 4x12, Neutral	7322540574814
793563	TENA Pants Super M 4x12p, NEU, NSW, Ps	7322541358413
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793631	TENA Pants Super L	7322540867350
793632	TENA Pants Super, L, 4x12, IT CODE	7322540893052
793634	TENA Pant Super Large, 4x10p, IT, CODE	7322541181905
793662	TENA Pants SUPER Larger, 4x12, Neutral	7322540574890
793663	TENA Pants Super L 4x12p, NEU, NSW, Ps	7322541358505
793670	ORLYS Pants SuperNoche G, 8x10p, ES, ProSkin	7322540910674
793671	TENA Pants Night Super L,8x10,NEU,NSW,PS	7322541214511
793672	TENA Pants Night Super L, 4x10p, OTC, PS	7322541214672
793673	TENA Pants Night Super Large, 2x30p, PS	7322541214795
793674	TENA Pants Night Super L,4x10,NEU,NSW,PS	7322541214511
793675	TENA Pants Night Super L,8x10,NEU,NSW,PS	7322541359861
793712	TENA Pants SUPER XL, 4x12	7322540630763
793713	TENA Pants Super XL, 4x12p, INT, Ps	7322541140193
793732	TENA Pants SUPER XL, 4x12	7322540630763
793762	TENA Pants SUPER XL, 4x12	7322540630763
793763	TENA Pants Super XL 4x12p, NEU, NSW, Ps	7322541358628
794510	TENA Pants MAXI Medium, 4x10	7322540574838
794512	TENA Pants Maxi Medium 4x10p, INT, Ps	7322541139753
794530	TENA Pants Maxi, M, 4x10, IT CODE	7322540893076
794532	TENA Pants Maxi Medium 4x8p, IT, CODE	7322541181950
794560	TENA Pants MAXI Medium, 4x10, Neutral	7322540574838
794561	TENA Pants Maxi M 4x10p, NEU, NSW, Ps	7322541358727
794610	TENA Pants MAXI Large, 4x10	7322540574913
794623	TENA Pants Maxi Large, 4x10p, INT, Ps	7322541139531
794630	TENA Pants Maxi, L, 4x10, IT CODE	7322540893090
794633	TENA Pants Maxi Large, 4x8p, IT, CODE	7322541182001
794660	TENA Pants MAXI Large, 4x10, Neutral	7322540574913
794661	TENA Pants Maxi Large 4x10p, NEU, NSW,Ps	7322541358826
794760	TENA Pants Maxi XL, 4x10, neutral	7322540765526
794761	TENA Pants Maxi XL, 4x10p, INT	7322541139739
794762	TENA Pants Maxi XL, 4x10p, NEU, NSW, Ps	7322541358925
796512	TENA Pants Plus Night M, 4x12	7322540839913
796513	TENA Pants Plus Night Medium,4x16p, Mega	7322540941142
796612	TENA Pants Plus Night L, 4x12	7322540839920

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Final Audit Report

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