

# 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 Gender Specific 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 73225401008472.

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

Mölndal, on January 2021-01-25



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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

**Essity Hygiene and Health AB**  
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Sweden  
Visitors' address: Mölndals Bro 2, Mölndal  
Phone: +46 31 746 00 00  
[www.essity.com](http://www.essity.com)

Document Name	Document ID	.....
Declaration of Conformity	FORM-00733	4.0

Article Number	Name	UDI-DI
100045	TENA Silh. Plus M, 56x1, Crème, A	7322541243467
100046	TENA Silh. Plus M, 56x1, Crème, B	7322541244426
100047	TENA Lady Pants Plus M, 56x1, Crème, C	7322541244488
100048	TENA Silh. Plus L, 56x1, Crème, A	7322541244532
100049	TENA Lady Pants Plus L, 56x1, Crème, C	7322541244587
100129	TENA Silh. Plus M, 56x1, Black, A	7322541244655
100131	TENA Silh. Plus M, 56x1, Black, B	7322541244723
100135	TENA Lady Pants Plus M, 56x1, Black, C	7322541244792
100136	TENA Silh. Plus L, 56x1, Black, A	7322541244860
100137	TENA Silh. Plus L, 56x1, Black, B	7322541244938
100140	TENA Lady Pants Plus L, 56x1, Black, C	7322541245027
100167	TENA Men Pants Plus M, 56x1, A	7322541247717
100168	TENA Men Pants Plus M, 56x1, B	7322541247779
100169	TENA Men Pants Plus M, 56x1, C	7322541247854
100171	TENA Men Pants Plus L, 56x1, A	7322541247892
100172	TENA Men Pants Plus L, 56x1, B	7322541247946
100173	TENA Men Pants Plus L, 56x1, C	7322541247991
100206	TENA Silh. Plus L, 56x1, Crème, B	7322541251400
100340	TENA Lady Slim Pants Normal M 63x1, C	7322541262840
100341	TENA Lady Slim Pants Normal L 63x1, C	7322541262895
100471	TENA Men Pants Plus M, 56x1, D	7322541319223
100472	TENA Men Pants Plus L, 56x1, D	7322541319315
100473	TENA Lady Pants Plus M, 56x1, Crème, CD mix	7322541319377
100474	TENA Lady Pants Plus L, 56x1, Crème, CD mix	7322541319421
100525	TENA LadySlim Pants Norm M 56x1 CDmix UA	7322541353586
100526	TENA LadySlim Pants Norm L 56x1 CDmix UA	7322541353739
703081	TENA Silhouette High Waist Noir Plus M 4x9p	7322541094540
703082	TENA Silhouette High Waist Noir Plus L 4x8p	7322541095028
703083	TENA Silhouette High Waist Noir Plus M 4x9p,FR,NL	7322541095035
703084	TENA Silhouette High Waist Noir Plus L 4x8p,FR,NL	7322541095066
703085	TENA Silhouette High Waist Noir Plus M 4x9,IT,ES	7322541095097
703086	TENA Silhouette High Waist Noir Plus L 4x8p,IT,ES	7322541095127

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	4.0

703087	TENA Silhouette High Waist Noir Plus M 4x9p, DE/ TENA Silhouette Plus Noir M 4x9p	7322541095158
703088	TENA Silhouette High Waist Noir Plus L 4x8p, DE/ TENA Silhouette Plus Noir L 4x8p	7322541095189
703122	TENA Silhouette High Waist Noir Plus L 2x8p SRP	7322541095028
703123	TENA Silhouette High Waist Noir Plus M 2x9p SRP	7322541094540
725264	TENA Lady Pants Plus M 4x9 Noir, East / OTC Edition	7322541130637
725265	TENA Lady Pants Plus L 2X30 Noir, East	7322541130712
725266	TENA Lady Pants Plus L 4x8 Noir, East / OTC Edition	7322541130750
725267	TENA Lady Pants Plus M 2X30 Noir, East	7322541130705
772509	TENA Men Pants Plus M, 4x9	7322540887624
772512	TENA Men Pants Plus M, 4x12	7322540887587
772513	TENA Men Pants Plus Medium / OTC Edition 4x9p	7322540920918
772514	TENA Men Pants Plus Medium 2x30p, East	7322540921205
772518	TENA Men Pants Plus Medium, 4x9p, MEA	7322540982084
772529	TENA Men Pants Plus M, 2x9	7322540887624
772608	TENA Men Pants Plus L, 4x8	7322540887648
772609	TENA Men Pants Plus Large / OTC Edition 4x8p	7322540920932
772610	TENA Men Pants Plus L, 4x10	7322540887600
772612	TENA Men Pants Plus Large 2x30p, East	7322540921229
772614	TENA Men Pants Plus Large, 4x8p, MEA	7322540982121
772628	TENA Men Pants Plus L, 2x8	7322540887648
782509	TENA Lady Pants Plus M, 4x9/ TENA Silhouette Lady Pants Plus M 4x9p/ TENA Silhouette High Waist Crème Plus M 4x9p	7322540887549
782510	TENA Lady Pants Plus Medium / OTC Edition 4x9p/ TENA Lady Pants Plus M 4x9p, Crème, East, OTC Edition	7322540920772
782511	TENA Lady Pants Plus Medium 2x30p, East/ TENA Lady Pants Plus M 2x30p, Crème, East	7322540921168
782512	TENA Lady Pants Plus M, 4x12/ TENA Silh. Lady Pants Plus M 4x12p INT/	7322540887402

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Declaration of Conformity	FORM-00733	4.0

	TENA Silhouette High Waist Crème Plus M 4x12p	
782516	TENA Lady Pants Plus Medium, 4x9p, MEA	7322540981605
782526	TENA Silhouette High Waist Crème Plus M 2x9p, SRP, DE	7322541065670
782527	TENA Silhouette High Waist Crème Plus M 4x9, ES,GR	7322541065632
782529	TENA Lady Pants Plus M, 2x9/ TENA Silh. Lady Pants Plus M 2x9p SRP/ TENA Silhouette High Waist Crème Plus M 2x9p SRP	7322540887549
782539	TENA Lady Pants Plus M, 4x9, FR,NL	7322540907216
782608	TENA Lady Pants Plus L, 4x8/ TENA Silhouette Lady Pants Plus L 4x8p/ TENA Silhouette High Waist Crème Plus L 4x8p	7322540887563
782609	TENA Lady Pants Plus Large / OTC Edition 4x8p/ TENA Lady Pants Plus L 4x8p, Crème, East, OTC Edition	7322540920796
782610	TENA Lady Pants Plus L, 4x10/ TENA Silh. Lady Pants Plus L 4x10p INT/ TENA Silhouette High Waist Crème Plus L 4x10p	7322540887525
782611	TENA Lady Pants Plus Large 2x30p, East/ TENA Lady Pants Plus L 2x30p, Crème, East	7322540921182
782614	TENA Lady Pants Plus Large, 4x8p, MEA	7322540982046
782615	TENA Silhouette High Waist Crème Plus L 2x9p, SRP, DE	7322541065694
782616	TENA Silhouette High Waist Crème Plus L 4x8p, ES,GR	7322541065656
782628	TENA Lady Pants Plus L, 2x8/ TENA Silh. Lady Pants Plus L 2x8p SRP/ TENA Silhouette High Waist Crème Plus L 2x8p SRP	7322540887563
782638	TENA Lady Pants Plus L, 4x8/ TENA Silhouette Plus Medium 4x9p FR/ TENA Silhouette High Waist Crème Plus L 4x8p,FR,NL	7322540907230
792113	TENA Lady Slim Pants Normal M 4x8,East	7322541226842
793109	TENA Lady Slim Pants Normal L 4x7,East	7322541226934

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# ES 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 Pants Gender Specific Inkontinenční kalhotky 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 41588, EMDN/CND kód je T04010103 a základní UDI-DI je 73225401008472.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

Mölndal, 25. ledna 2021

[podpis]

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Romana Stefek

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

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

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**

Název dokumentu	ID dokumentu	
Prohlášení o shodě	FORMULÁŘ 00733	4.0

Číslo položky	Název	UDI-DI
100045	TENA Silh. Plus M, 56x1, Crème, A	7322541243467
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