

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 Laminate Pants 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 73225401008676.

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

Mölndal, on January 2021-01-22



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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.

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Seat: Göteborgs kommun. Registration number: SE556007-2356

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

Article Number	Name	UDI-DI
54950	TENA Pants Discreet Plus XL 4x14 MEA	380040549500
100034	TENA Silh. Normal M 72x1 Whi.pri LW, A	7322541242996
100035	TENA Silh. Normal M 72x1 Whi.pri LW, B	7322541243108
100036	TENA Silh. Normal M 72x1 Whi.pri LW, C	7322541243511
100037	TENA Silh. Normal L 72x1 Whi.pri LW, A	7322541243672
100038	TENA Silh. Normal L 72x1 Whi.pri LW, B	7322541243795
100039	TENA Silh. Normal M 72x1, Black LW, A	7322541243887
100041	TENA Silh. Normal M 72x1, Black LW, B	7322541243979
100042	TENA Silh. Normal L 72x1 Whi.pri LW, C	7322541244198
100043	TENA Silh. Normal L 72x1, Black LW, A	7322541244297
100044	TENA Silh. Normal L 72x1, Black LW, B	7322541244396
100176	TENA Men PU L4 M, 56x1, A	7322541248646
100177	TENA Men PU L4 M, 56x1, B	7322541248752
100178	TENA Men PU L4 M, 56x1, C	7322541248868
100179	TENA Men PU L4 L, 56x1, A	7322541248981
100180	TENA Men PU L4 L, 56x1, B	7322541249100
100181	TENA Men PU L4 L, 56x1, C	7322541249322
100475	TENA Lady Pant Disc Plus XL 40x1, MEA, D	7322541319445
100540	TENA Lady Pant Disc Plus M 63x1, MEA, D	7322541380056
100541	TENA Lady Pant Disc Plus L 63x1, MEA, D	7322541380247
795506	TENA Silhouette Normal Low Waist Blanc M, 6x6 SRP	7322540679137
795509	TENA Silhouette Normal Low Waist Blanc M 6x6 eC	7322540897081
795510	TENA Silhouette Normal Low Waist Noir M, 3x10 SRP	7322541056494
795511	TENA Silhouette Normal Low Waist Noir M, 6x10, FR	7322541056531
795512	TENA Silhouette Normal Low Waist Blanc M, 6x12	7322540488258
795514	TENA Silhouette Normal Low Waist Blanc M, 6x12, NEU	7322540488258
795515	TENA Silhouette Normal Low Waist Noir M, 3x10, CODE	7322541056579
795516	TENA Silhouette Normal Low Waist Noir M, 6x10	7322541056494
795520	TENA Discr Norm M 3x10 SRP Black LW, AUS	7322541216508
795521	TENA Silh. Norm M 6x6 Whi.pr LW,RTeC,NEU	7322541313603
795522	TENA Silhouette Normal Low Waist Blanc M, 6x12, CODE, IT	7322540488258
795532	TENA Silhouette Normal Low Waist Blanc M, 6x12, FR	7322540532852
795605	TENA Silhouette Normal Low Waist Blanc L, 6x5 SRP	7322540679212
795608	TENA Silhouette Normal Low Waist Blanc L 6x5 eC	7322540897074
795610	TENA Silhouette Normal Low Waist Blanc L, 6x10	7322540488555
795614	TENA Silhouette Normal Low Waist Blanc L, 6x10, NEU	7322540488555
795616	TENA Silhouette Normal Low Waist Noir L, 3x9 SRP	7322541056708
795617	TENA Silhouette Normal Low Waist Noir L, 6x9, FR	7322541056746
795619	TENA Silhouette Normal Low Waist Noir L, 3x9, CODE	7322541056784

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795623	TENA Discr Norm L 3x9 SRP Black LW, AUS	7322541216607
795620	TENA Silhouette Normal Low Waist Blanc L, 6x10, CODE, IT	7322540488555
795621	TENA Silhouette Normal Low Waist Noir L, 6x9	7322541056708
795626	TENA Silh. Norm L 6x5 Whi.pr LW,RTeC,NEU	7322541313795
795630	TENA Silhouette Normal Low Waist Blanc L, 6x10, FR	7322540532876
796010	TENA Silhouette Normal Low Waist Blanc L, 3x10 SRP	7322540819304
796012	TENA Silhouette Normal Low Waist Blanc M, 3x12 SRP	7322540819281
797508	TENA Lady Silhouette Nuit Medium	7322540679151
797512	TENA Silhouette Discreet Plus High Waist Blanc M, 6x12	7322540483529
797513	TENA Silh Lady Pant Disc Plus M 6x12 MEA	7322540993219
797518	TENA Silhouette Night High Waist Blanc M, 6x8	7322540822120
797519	TENA Lady Pants Night M, 6x8p, South	7322540968163
797605	TENA Lady Pants Night Large, SRP	7322540679250
797607	TENA Lady Silhouette Nuit Large	7322540679236
797610	TENA Silhouette Discreet Plus High Waist Blanc L, 6x10	7322540483567
797613	TENA Silh Lady Pant Disc Plus L 6x10 MEA	7322540993318
797617	TENA Silhouette Night High Waist Blanc L, 6x7	7322540822144
797618	TENA Lady Pants Night L, 6x7pcs, South	7322540968255
798300	TENA Men Protective Underwear L4 M/L	7322540483970
798306	TENA Men PU L4 L 4x10, Int.	7322540886238
798307	TENA Men PU L4 L 3x8, Int. (SRP)	7322540886252
798308	TENA Men PU L4 M 4x12, Int.	7322540886276
798309	TENA Men PU L4 M 3x10, Int. (SRP)	7322540886290
798310	TENA Men PU L4 L 4x10, Neutral Box	7322540886238
798311	TENA Men PU L4 L 4x10, IT Sticker	7322540886238
798312	TENA Men PU L4 M 4x12, Neutral Box	7322540886276
798313	TENA Men PU L4 M 4x12, IT Sticker	7322540886276
798314	TENA Men PU L4 L 4x10, eC	7322540897098
798315	TENA Men PU L4 M 4x12, eC	7322540897104
798316	TENA Men PU L4 Large 4x10p, MEA	7322540936254
798319	TENA Men PU L4 M 4x10, IT	7322541201078
798321	TENA Men PU L4 L 4x8, IT	7322541201139
798340	TENA Pants Men Large	7322540549034

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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 Laminate Pants 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 73225401008676.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

Mölndal, 22. 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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Název dokumentu	ID dokumentu	Verze
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