

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 Pants Gender Specific

Basic UDI-DI: 73225401008472

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: 41588

EMDN code: T04010103

Signatory: Mölndal, on Jul 5, 2024



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

* 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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 Sweden
 Visitors' address: Mölndals Bro 2, Mölndal
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www.essity.com

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

Article Number	Article 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 S/M Blue, 56x1, A	7322541247717
100168	TENA Men Pants Plus S/M Blue, 56x1, B	7322541247779
100169	TENA Men Pants Plus S/M Blue, 56x1, C	7322541247854
100171	TENA Men Pants Plus L/XL, 56x1 Bleu, A	7322541247892
100172	TENA Men Pants Plus L/XL Blue, 56x1, B	7322541247946
100173	TENA Men Pants Plus L/XL Blue, 56x1, C	7322541247991
100206	TENA Silh. Plus L, 56x1, Crème, B	7322541251400
100471	TENA Men Pants Plus S/M Blue, 56x1, D	7322541319223
100472	TENA Men Pants Plus L/XL Blue, 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
100681	TENA Men Pants N S/M Grey, 56x1, A	7322541905082
100682	TENA Men Pants N S/M Grey, 56x1, B	7322541905389
100683	TENA Men Pants N S/M Grey, 56x1, C	7322541905525
100712	TENA Men Pants N L/XL, 56x1 Grey, A	7322541905556
100713	TENA Men Pants N L/XL Grey, 56x1, B	7322541905631
100714	TENA Men Pants N L/XL Grey, 56x1, C	7322541905693
101004	TENA Lady Pants Plus M 56x1, Crème, East	7322542387863
101005	TENA Silh. Classic PlusM 56x1 Crème West	7322542388013
101006	TENA Silh. Classic PlusL 56x1 Crème West	7322542388099
101043	TENA Lady Pants Plus L 56x1, Crème, East	7322542387948
101046	TENA Lady Pants Plus M 56x1 Black, East	7322542388334
101047	TENA Lady Pants Plus L 56x1 Black, East	7322542388426
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 4x9p,IT,ES	7322541095097
703086	TENA Silhouette High Waist Noir Plus L 4x8p,IT,ES	7322541095127
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

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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 S/M, 4x9p, Blue	7322540887624
772512	TENA Men Pants Plus S/M, 4x12p, Blue	7322540887587
772513	TENA Men Pants Plus S/M, 4x9p,Blue,OTC	7322540920918
772514	TENA Men Pants Plus S/M 2x30p,Blue, East	7322540921205
772518	TENA Men Pants Plus Medium, 4x9p, MEA	7322540982084
772522	TENA Men Pants Plus S/M, 4x12p, NEU,Blue	7322541745640
772529	TENA Men Pants Plus S/M 2x9p, Blue SRP	7322540887624
772533	TENA Men Pants Plus S/M,2x9,SRP,Blue,AUS	7322541106328
772608	TENA Men Pants Plus L/XL, 4x8p, Blue	7322540887648
772609	TENA Men Pants Plus L/XL, 4x8p,Blue,OTC	7322540920932
772610	TENA Men Pants Plus L/XL, 4x10p,Blue	7322540887600
772612	TENA Men Pants Plus L/XL 2x30p,Blue,East	7322540921229
772614	TENA Men Pants Plus Large, 4x8p, MEA	7322540982121
772628	TENA Men Pants Plus L/XL, 2x8p,Blue,SRP	7322540887648
772629	TENA Men Pants Plus L/XL,2x8,Blue,AUS	7322541106434
772640	TENA Men Pants Plus L/XL, 4x10p, NEU,Blue	7322541745763
772701	TENA Men Pants Normal S/M 2x9,Grey SRP	7322541679693
772702	TENA Men Pants Normal S/M 4x12,Grey,INT	7322541679815
772703	TENA Men Pants Normal S/M 4x9,Grey,OTC	7322541679754
772704	TENA Men Pants Normal S/M 2x30,Grey	7322541679792
772801	TENA Men Pants Normal L/XL 2x8,Grey,SRP	7322541679853
772802	TENA Men Pants Normal L/XL 4x10,Grey,INT	7322541679891
772803	TENA Men Pants Normal L/XL 4x8,Grey,OTC	7322541679938
772804	TENA Men Pants Normal L/XL 2x30,Grey	7322541679976
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/ TENA Silhouette High Waist Crème Plus M 4x12p	7322540887402
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
782532	TENA Discreet Super M 2x9p SRP Crème AUS	7322541105055
782539	TENA Lady Pants Plus M, 4x9, FR,NL	7322540907216
782560	TENA Lady Pants Plus M 4x9p, Crème, East	7322542294765
782561	TENA Lady Pants Plus M 2x30p Crème, East	7322542294840
782563	TENA Silh. Classic Plus M 4x9p Crème	7322542433126
782564	TENA Silh. Classic Plus L 4x8p Crème	7322542433232

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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
782629	TENA Discreet Super L 2x8p SRP Crème AUS	7322541105147
782638	TENA Lady Pants Plus L, 4x8/ TENA Silhouette Plus Medium 4x9p FR/ TENA Silhouette High Waist Crème Plus L 4x8p,FR,NL	7322540907230
782680	TENA Lady Pants Plus L 4x8p, Crème, East	7322542297360
782682	TENA Lady Pants Plus L 2x30p Crème, East	7322542297544
785270	TENA Lady Pants Plus M 4x9 Black, East	7322542295397
785271	TENA Lady Pants Plus M 2X30 Black, East	7322542295489
785290	TENA Lady Pants Plus L 2X30 Black, East	7322542298046
785291	TENA Lady Pants Plus L 4x8 Black, East	7322542298190
792113	TENA Lady Slim Pants Normal M 4x8,East	7322541226842
793109	TENA Lady Slim Pants Normal L 4x7,East	7322541226934

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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 Pants Gender Specific

Basic UDI-DI: 73225401008472

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: 41588
EMDN kód: T04010103

Signatory:

Mölndal, dne 5.7.2024
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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Číslo položek	Položka	UDI-DI číslo
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 S/M Blue, 56x1, A	7322541247717
100168	TENA Men Pants Plus S/M Blue, 56x1, B	7322541247779
100169	TENA Men Pants Plus S/M Blue, 56x1, C	7322541247854
100171	TENA Men Pants Plus L/XL, 56x1 Bleu, A	7322541247892
100172	TENA Men Pants Plus L/XL Blue, 56x1, B	7322541247946
100173	TENA Men Pants Plus L/XL Blue, 56x1, C	7322541247991
100206	TENA Silh. Plus L, 56x1, Crème, B	7322541251400
100471	TENA Men Pants Plus S/M Blue, 56x1, D	7322541319223
100472	TENA Men Pants Plus L/XL Blue, 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
100681	TENA Men Pants N S/M Grey, 56x1, A	7322541905082
100682	TENA Men Pants N S/M Grey, 56x1, B	7322541905389
100683	TENA Men Pants N S/M Grey, 56x1, C	7322541905525
100712	TENA Men Pants N L/XL, 56x1 Grey, A	7322541905556
100713	TENA Men Pants N L/XL Grey, 56x1, B	7322541905631
100714	TENA Men Pants N L/XL Grey, 56x1, C	7322541905693
101004	TENA Lady Pants Plus M 56x1, Crème, East	7322542387863
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101006	TENA Silh. Classic PlusL 56x1 Crème West	7322542388099
101043	TENA Lady Pants Plus L 56x1, Crème, East	7322542387948
101046	TENA Lady Pants Plus M 56x1 Black, East	7322542388334
101047	TENA Lady Pants Plus L 56x1 Black, East	7322542388426
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
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

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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 S/M, 4x9p, Blue	7322540887624
772512	TENA Men Pants Plus S/M, 4x12p, Blue	7322540887587
772513	TENA Men Pants Plus S/M, 4x9p,Blue,OTC	7322540920918
772514	TENA Men Pants Plus S/M 2x30p,Blue, East	7322540921205
772518	TENA Men Pants Plus Medium, 4x9p, MEA	7322540982084
772522	TENA Men Pants Plus S/M, 4x12p, NEU,Blue	7322541745640
772529	TENA Men Pants Plus S/M 2x9p, Blue SRP	7322540887624
772533	TENA Men Pants Plus S/M,2x9,SRP,Blue,AUS	7322541106328
772608	TENA Men Pants Plus L/XL, 4x8p, Blue	7322540887648
772609	TENA Men Pants Plus L/XL, 4x8p,Blue,OTC	7322540920932
772610	TENA Men Pants Plus L/XL, 4x10p,Blue	7322540887600
772612	TENA Men Pants Plus L/XL 2x30p,Blue,East	7322540921229
772614	TENA Men Pants Plus Large, 4x8p, MEA	7322540982121
772628	TENA Men Pants Plus L/XL, 2x8p,Blue,SRP	7322540887648
772629	TENA Men Pants Plus L/XL,2x8,Blue,AUS	7322541106434
772640	TENA Men Pants Plus L/XL, 4x10p, NEU,Blue	7322541745763
772701	TENA Men Pants Normal S/M 2x9,Grey SRP	7322541679693
772702	TENA Men Pants Normal S/M 4x12,Grey,INT	7322541679815
772703	TENA Men Pants Normal S/M 4x9,Grey,OTC	7322541679754
772704	TENA Men Pants Normal S/M 2x30,Grey	7322541679792
772801	TENA Men Pants Normal L/XL 2x8,Grey,SRP	7322541679853
772802	TENA Men Pants Normal L/XL 4x10,Grey,INT	7322541679891
772803	TENA Men Pants Normal L/XL 4x8,Grey,OTC	7322541679938
772804	TENA Men Pants Normal L/XL 2x30,Grey	7322541679976
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/ TENA Silhouette High Waist Crème Plus M 4x12p	7322540887402
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
782532	TENA Discreet Super M 2x9p SRP Crème AUS	7322541105055
782539	TENA Lady Pants Plus M, 4x9, FR,NL	7322540907216
782560	TENA Lady Pants Plus M 4x9p, Crème, East	7322542294765
782561	TENA Lady Pants Plus M 2x30p Crème, East	7322542294840
782563	TENA Silh. Classic Plus M 4x9p Crème	7322542433126
782564	TENA Silh. Classic Plus L 4x8p Crème	7322542433232

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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
782629	TENA Discreet Super L 2x8p SRP Crème AUS	7322541105147
782638	TENA Lady Pants Plus L, 4x8/ TENA Silhouette Plus Medium 4x9p FR/ TENA Silhouette High Waist Crème Plus L 4x8p,FR,NL	7322540907230
782680	TENA Lady Pants Plus L 4x8p, Crème, East	7322542297360
782682	TENA Lady Pants Plus L 2x30p Crème, East	7322542297544
785270	TENA Lady Pants Plus M 4x9 Black, East	7322542295397
785271	TENA Lady Pants Plus M 2X30 Black, East	7322542295489
785290	TENA Lady Pants Plus L 2X30 Black, East	7322542298046
785291	TENA Lady Pants Plus L 4x8 Black, East	7322542298190
792113	TENA Lady Slim Pants Normal M 4x8,East	7322541226842
793109	TENA Lady Slim Pants Normal L 4x7,East	7322541226934

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