

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 Fixation 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 35120, the EMDN/CND code is T04010104 and the Basic UDI-DI is 7322540100997F.

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

Mölndal, on January 2021-01-26



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

Article Number	Article	UDI-DI
100454	TENA Fix Original M 60x1 pcs	7322541308968
100492	TENA Fix XS 50x1p	7322541325965
100493	TENA Fix XL 50x1p	7322541326009
100494	TENA Fix XXL 50x1p	7322541326047
100495	TENA Fix 3XL 50x1p	7322541326085
100496	TENA Fix 4XL 40x1p	7322541326122
100497	TENA Fix 5XL 40x1p	7322541326160
100502	TENA Fix S 50x1 pcs	7322541330556
100503	TENA Fix M 50x1 pcs	7322541330617
100504	TENA Fix L 50x1 pcs	7322541330679
100505	TENA Fix Acute S 60x1 pcs	7322541330730
100506	TENA Fix Acute M 60x1 pcs	7322541330792
100507	TENA Fix Acute L 60x1 pcs	7322541330853
100508	TENA Fix AcuteXL 60x1 pcs	7322541331010
100509	TENA Fix Original S 60x1 pcs	7322541331072
100510	TENA Fix Original L 60x1 pcs	7322541331133
702601	TENA Panty Feminine White S	7322540481006
702602	TENA Panty Feminine White M	7322540489583
702603	TENA Panty Feminine White L	7322540489606
702604	TENA Panty Feminine White XL	7322540489729
702605	TENA Panty Feminine Black S	7322540489743
702606	TENA Panty Feminine Black M	7322540489767
702607	TENA Panty Feminine Black L	7322540489781
702608	TENA Panty Feminine Black XL	7322540489804
702617	TENA Panty Feminine White XXL	7322540653595
702618	TENA Panty Feminine Black XXL	7322540653816
754023	TENA Fix S 20x5 p	7322540419412
754024	TENA Fix M 20x5 p	7322540419436
754025	TENA Fix L 20x5 p	7322540419511
754026	TENA Fix XL 20x5 p	7322540419474
754027	TENA Fix XXL 20x5 p	7322540419498
754028	TENA Fix S 8x25 p	7322540419528
754029	TENA Fix M 8x25 p	7322540419542
754030	TENA Fix L 8x25 p	7322540419566
754031	TENA Fix XL 8x25 p	7322540419627
754032	TENA Fix XXL 8x25 p	7322540419603
754033	TENA Fix XS	7322540494662
754035	TENA Fix M 1x25 p	7322540419542
754036	TENA Fix L 1x25 p	7322540419566
754037	TENA Fix XL 1x25 p	7322540419627

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754038	TENA Fix XXL 1x25 p	7322540419603
754047	TENA Fix 3XL 20x5 p	7322540735840
754049	TENA Fix XS 20x5 p NEU	7322540494662
754052	TENA Fix XXL 20x5 p NEU	7322540419498
754053	TENA Fix XXL 8x25 p NEU	7322540419603
754054	TENA Fix S 20x5 p NEU	7322540419412
754055	TENA Fix S 8x25 p NEU	7322540419528
754056	TENA Fix M 20x5 p NEU	7322540419436
754057	TENA Fix M 8x25 p NEU	7322540419542
754058	TENA Fix L 20x5 p NEU	7322540419511
754059	TENA Fix L 8x25 p NEU	7322540419566
754060	TENA Fix XL 20x5 p NEU	7322540419474
754061	TENA Fix XL 8x25 p Neu	7322540419627
754062	TENA Fix 3XL 20x5 p NEU	7322540735840
754063	TENA Stretch Panty S	7322540800999
754064	TENA Stretch Panty M	7322540801217
754065	TENA Stretch Panty L	7322540801231
754066	TENA Stretch Panty XL	7322540801255
754067	TENA Fix 4XL	7322540934090
754068	TENA Fix 5XL	7322540934137
754069	TENA Fix Cotton Special 3XL 24x1pcs	7322540998597
754070	TENA Fix Acue Onesize 1x250p	7322540963717
754071	TENA Fix Acue S 1x250p	7322540963762
754072	TENA Fix Acue M 1x250p	7322540963816
754073	TENA Fix Acue L 1x250p	7322540963861
754074	TENA Fix Acue XL 1x200p	7322540963915
754075	TENA Stretch Panty XXL 15x4p	7322540998610
754076	TENA Stretch Panty 3XL 15x4p	7322540998634
754077	TENA Fix Basic 3XL 100x5pcs	7322540998719
754078	TENA Fix Acute S, 10x25pcs	7322540998788
754079	TENA Fix Acute M, 10x25pcs	7322540998825
754080	TENA Fix Acute L, 10x25pcs	7322540998863
754081	TENA Fix Acute XL, 8x25pcs	7322540998900
754082	TENA Fix Acute XXL, 8x25pcs	7322540998948
754083	TENA Fix Acute 3XL, 8x25pcs	7322540998986
755382	TENA Fix Acute one size	7310791220819
755402	TENA Fix Original S	7322540728927
755501	TENA Fix Original M	7322540728941
755504	TENA Fix Original M	7310791205151
755520	TENA Fix Original M	7310791039749
755612	TENA Fix Original	7322540728965
755613	TENA Fix Original XL, 5x25pcs	7322541229041

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755614	TENA Fix Original XXL, 5x25pcs	7322541229812
755615	TENA Fix Original 3XL, 5x25pcs	7322541229829
755622	TENA Fix Original L	7310791271668
756602	TENA Fix Cotton Special XS	7322540564587
756603	TENA Fix Cotton Special S	7322540564600
756604	TENA Fix Cotton Special M	7322540565720
756605	TENA Fix Cotton Special XS/S 9x5p JP	7322540260854
756606	TENA Fix Cotton Special L	7322540565744
756607	TENA Fix Cotton Special XL	7322540565768
756608	TENA Fix Cotton Special XXL	7322540565782
756705	TENA Fix Cotton Special S/M 7x5p JP	7322540261042
756801	TENA Fix Cotton special L/XL	7310791281711
756805	TENA Fix Cotton Special L/XL 7x5p JP	7322540261134
756901	TENA Fix Cotton special XXL	7310791281742
756905	TENA Fix Cotton Special XXL 5x5p JP	7322540261226
768402	TENA Fix Basic S 1x200p	7322540964479
768403	TENA Fix Basic M 1x200p	7322540964509
768404	TENA Fix Basic L 1x200p	7322540964530
768405	TENA Fix Basic XL 1x200p	7322540964561
768406	TENA Fix Basic XXL 1x200p	7322540964592
768431	TENA Fix Basic S 100x5 p	7310791047768
768531	TENA Fix Basic M 100x5 p	7310791047775
768631	TENA Fix Basic L 100x5 p	7310791047782
768731	TENA Fix Basic XL 100x5 p	7310791047799
768831	TENA Fix Basic XXL 100x5 p	7322540012873

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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 Fixation 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 35120, EMDN/CND kód je T04010104 a základní UDI-DI je
7322540100997F.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

Mölndal, 26. 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.

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

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Švédsko

Adresa pro návštěvy:
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Tel.: +46 31 746 00 00
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Název dokumentu	ID dokumentu	Verze
Prohlášení o shodě	FORMULÁŘ 00733	4.0

Číslo položky	Položka	UDI-DI
100454	TENA Fix Original M 60x1 pcs	7322541308968
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755612	TENA Fix Original	7322540728965
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768531	TENA Fix Basic M 100x5 p	7310791047775
768631	TENA Fix Basic L 100x5 p	7310791047782
768731	TENA Fix Basic XL 100x5 p	7310791047799
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