

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 Fixation Pants

Basic UDI-DI: 7322540100997F

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: 35120

EMDN code: T04010104

Signatory: Mölndal, on 2022-04-07



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

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 Sweden
 Visitors' address: Mölndals Bro 2, Mölndal
 Phone: +46 31 746 00 00
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* 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

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

Article number	Article Name	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
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
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

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Declaration of Conformity	FORM-00733	6.0

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
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
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

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756805	TENA Fix Cotton Special L/XL 7x5p JP	7322540261134
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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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 Fixation Pants

Basic UDI-DI: 7322540100997F

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: 35120
EMDN kód: T04010104

Signatory:

Mölndal, dne 7.4.2022
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
100454	TENA Fix Original M 60x1 pcs	7322541308968
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