

# 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

\* 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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| Document Name             | Document ID | Version |
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| 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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| 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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