

# 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 Flex

**Basic UDI-DI:** 7322540100726T

**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:** 11239

**EMDN code:** T04010103

**Signatory:** Mölndal, on 2022-06-27



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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| Article number | Article                            | UDI-DI number |
|----------------|------------------------------------|---------------|
| 100008         | TENA Flex Maxi Large 48x1pcs AB    | 7322541218328 |
| 100269         | TENA Flex Plus Medium 60x1pcs AB   | 7322541257778 |
| 100270         | TENA Flex Super Large 60x1pcs AB   | 7322541257884 |
| 100404         | TENA Flex Plus XL 60x1pcs AB       | 7322541280011 |
| 100405         | TENA Flex Plus Small 60x1pcs AB    | 7322541280158 |
| 100406         | TENA Flex Plus Medium 60x1pcs ES   | 7322541280240 |
| 100407         | TENA Flex Plus Large 60x1pcs ES    | 7322541280363 |
| 100408         | TENA Flex Plus Large 60x1pcs AB    | 7322541280479 |
| 100409         | TENA Flex Normal Medium 68x1pcs AB | 7322541280561 |
| 100410         | TENA Flex Normal Large 68x1pcs AB  | 7322541280653 |
| 100411         | TENA Flex Maxi XL 48x1pcs AB       | 7322541280783 |
| 100412         | TENA Flex Maxi Small 48x1pcs AB    | 7322541280929 |
| 100413         | TENA Flex Maxi Medium 48x1pcs AB   | 7322541281032 |
| 100437         | TENA Flex Ultima XL 40x1pcs AB     | 7322541293769 |
| 100438         | TENA Flex Ultima Small 40x1pcs AB  | 7322541293868 |
| 100439         | TENA Flex Ultima Medium 40x1pcs AB | 7322541293974 |
| 100440         | TENA Flex Ultima Large 40x1pcs AB  | 7322541294087 |
| 100441         | TENA Flex Super XL 60x1pcs AB      | 7322541294193 |
| 100442         | TENA Flex Super Small 60x1pcs AB   | 7322541294339 |
| 100443         | TENA Flex Super Medium 60x1pcs ES  | 7322541294452 |
| 100444         | TENA Flex Super Medium 60x1pcs AB  | 7322541294568 |
| 100445         | TENA Flex Super Large 60x1pcs ES   | 7322541294681 |
| 100455         | TENA Flex Plus Medium 60x1pcs C    | 7322541309514 |
| 100456         | TENA Flex Plus Large 60x1pcs C     | 7322541309620 |
| 100457         | TENA Flex Super Medium 60x1pcs C   | 7322541309736 |
| 100458         | TENA Flex Super Large 60x1pcs C    | 7322541309842 |
| 100459         | TENA Flex Maxi Medium 48x1pcs C    | 7322541309958 |
| 100460         | TENA Flex Maxi Large 48x1pcs C     | 7322541310169 |
| 100630         | TENA Flex Ultima XL 40x1pcs AB     | 7322541775371 |
| 100631         | TENA Flex Ultima Small 40x1pcs AB  | 7322541785462 |
| 100632         | TENA Flex Ultima Medium 40x1pcs AB | 7322541783994 |
| 100633         | TENA Flex Ultima Large 40x1pcs AB  | 7322541784090 |
| 100634         | TENA Flex Super XL 60x1pcs AB      | 7322541784748 |
| 100635         | TENA Flex Super Small 60x1pcs AB   | 7322541784830 |
| 100636         | TENA Flex Super Medium 60x1pcs ES  | 7322541784939 |
| 100637         | TENA Flex Super Medium 60x1pcs AB  | 7322541785455 |
| 100638         | TENA Flex Super Large 60x1pcs ES   | 7322541785219 |
| 100639         | TENA Flex Plus XL 60x1pcs AB       | 7322541795546 |
| 100640         | TENA Flex Plus Small 60x1pcs AB    | 7322541795652 |
| 100641         | TENA Flex Plus Medium 60x1pcs ES   | 7322541795751 |
| 100642         | TENA Flex Plus Large 60x1pcs ES    | 7322541795843 |

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| 100643 | TENA Flex Plus Large 60x1pcs AB          | 7322541795942 |
| 100644 | TENA Flex Normal Medium 68x1pcs AB       | 7322541796055 |
| 100645 | TENA Flex Normal Large 68x1pcs AB        | 7322541796161 |
| 100646 | TENA Flex Maxi XL 48x1pcs AB             | 7322541796277 |
| 100647 | TENA Flex Maxi Small 48x1pcs AB          | 7322541796383 |
| 100648 | TENA Flex Maxi Medium 48x1pcs AB         | 7322541796499 |
| 100649 | TENA Flex Maxi Large 48x1pcs AB          | 7322541796604 |
| 100650 | TENA Flex Plus Medium 60x1pcs AB         | 7322541796772 |
| 100651 | TENA Flex Super Large 60x1pcs AB         | 7322541796888 |
| 100652 | TENA Flex Plus Medium 60x1pcs C          | 7322541797137 |
| 100653 | TENA Flex Plus Large 60x1pcs C           | 7322541797298 |
| 100654 | TENA Flex Super Medium 60x1pcs C         | 7322541797380 |
| 100655 | TENA Flex Super Large 60x1pcs C          | 7322541797489 |
| 100656 | TENA Flex Maxi Medium 48x1pcs C          | 7322541797571 |
| 100657 | TENA Flex Maxi Large 48x1pcs C           | 7322541797663 |
| 720000 | TENA Flex Belt Extension 12x10pcs        | 7322540065091 |
| 720240 | TENA Flex Elastico Plus M 4x20p, ProSkin | 7310791260297 |
| 720349 | TENA Flex Elastico Plus L 4x20p,ProSkin  | 7322540036459 |
| 720421 | TENA Flex Elastico Super M 4x20p,ProSkin | 7322540928297 |
| 720422 | TENA Flex Plus Small 3x30pcs, JP         | 7322541014906 |
| 720430 | TENA Flex Plus Medium 3x30pcs, JP        | 7322541015002 |
| 720512 | TENA Flex Plus Large 3x30pcs, JP         | 7322541015101 |
| 720513 | TENA Flex Plus S 3x30p, IT               | 7322541086835 |
| 720514 | TENA Flex Plus S 3x30p, INT/NEU NSW      | 7322540125283 |
| 720515 | TENA Flex Plus M 3x30p, IT               | 7322541087160 |
| 720516 | TENA Flex Plus M 3x30p, INT/NEU NSW      | 7322540054651 |
| 720517 | TENA Flex Plus L 3x30p, IT               | 7322541087467 |
| 720518 | TENA Flex Plus L 3x30p, INT/NEU NSW      | 7322540054675 |
| 720519 | TENA Flex Plus XL 3x30p, INT/NEU NSW     | 7322540202519 |
| 720520 | TENA Flex Elastico Plus M 4x20p,ProSkin  | 7322541422817 |
| 720521 | TENA Flex Elastico Plus L 4x20p,ProSkin  | 7322541422930 |
| 720522 | TENA Flex Elastico Super M 4x20p,ProSkin | 7322541423043 |
| 720523 | TENA Flex Elastico Super L 4x20p,ProSkin | 7322541423166 |
| 722234 | TENA Flex Normal M 3x34p, INT            | 7322540769838 |
| 722334 | TENA Flex Normal L 3x34p, INT            | 7322540769852 |
| 722360 | TENA Flex Normal M 3x34p, INT/NEU NSW    | 7322540769838 |
| 722393 | TENA Flex Normal L 3x34p, INT/NEU NSW    | 7322540769852 |
| 722394 | TENA Flex Normal L 3x34p INT/NEU NSW     | 7322541405537 |
| 722514 | TENA Flex Normal L 3x34p INT NSW         | 7322541405537 |
| 723130 | TENA Flex Plus S 3x30p, INT              | 7322540125283 |
| 723230 | TENA Flex Plus M 3x30p, INT              | 7322540054651 |
| 723330 | TENA Flex Plus L 3x30p, INT              | 7322540054675 |

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| 723333 | TENA Flex Plus L 3x30p INT NSW            | 7322541405759 |
| 723430 | TENA Flex Plus XL 3x30p, INT              | 7322540202519 |
| 724052 | TENA Flex Super Small 3x30pcs, JP         | 7322541015231 |
| 724130 | TENA Flex Super S 3x30p, INT              | 7322540394467 |
| 724230 | TENA Flex Super M 3x30p, INT              | 7322540390575 |
| 724320 | TENA Flex Super Medium 3x30pcs, JP        | 7322541015323 |
| 724321 | TENA Flex Super Large 3x30pcs, JP         | 7322541015439 |
| 724330 | TENA Flex Super L 3x30p, INT              | 7322540390599 |
| 724340 | TENA Flex Elastico Super L 4x20p, ProSkin | 7322540054712 |
| 724430 | TENA Flex Super XL 3x30p, INT             | 7322540398724 |
| 724857 | TENA Flex Super S 3x30p, IT               | 7322541087917 |
| 724900 | TENA Flex Super S 3x30p, INT/NEU NSW      | 7322540394467 |
| 724901 | TENA Flex Super M 3x30p, IT               | 7322541088167 |
| 724910 | TENA Flex Super M 3x30p, INT/NEU NSW      | 7322540390575 |
| 724920 | TENA Flex Super L 3x30p, IT               | 7322541088365 |
| 724930 | TENA Flex Super L 3x30p, INT/NEU NSW      | 7322540390599 |
| 724940 | TENA Flex Super XL 3x30p, INT/NEU NSW     | 7322540398724 |
| 724950 | TENA Flex Plus XL 3x30p INT NSW           | 7322541404646 |
| 724960 | TENA Flex Plus XL 3x30p INT/NEU NSW       | 7322541404646 |
| 724970 | TENA Flex Super XL 3x30p INT/NEU NSW      | 7322541404967 |
| 724980 | TENA Flex Super XL 3x30p INT NSW          | 7322541404967 |
| 725000 | TENA Flex Maxi XL 3x21p INT NSW           | 7322541405209 |
| 725122 | TENA Flex Maxi S 3x22p, INT               | 7322540129489 |
| 725130 | TENA Flex Ultima S 3x20pcs, INT/NEU NSW   | 7322540884814 |
| 725194 | TENA Flex Maxi Small 3x22pcs, JP          | 7322541015569 |
| 725195 | TENA Flex Maxi Medium 3x22pcs, JP         | 7322541015668 |
| 725196 | TENA Flex Maxi Large 3x22pcs, JP          | 7322541015767 |
| 725220 | TENA Flex Ultima M 3x20p, INT/NEU NSW     | 7322540614893 |
| 725222 | TENA Flex Maxi M 3x22p, INT               | 7322540079258 |
| 725228 | TENA Flex Maxi S 3x22p, INT/NEU NSW       | 7322540129489 |
| 725229 | TENA Flex Maxi M 3x22p, INT/NEU NSW       | 7322540079258 |
| 725230 | TENA Flex Maxi L 3x22p, INT/NEU NSW       | 7322540079296 |
| 725231 | TENA Flex Maxi XL 3x21p, INT/NEU NSW      | 7322540118971 |
| 725320 | TENA Flex Ultima L 3x20p, INT/NEU NSW     | 7322540615418 |
| 725322 | TENA Flex Maxi L 3x22p, INT               | 7322540079296 |
| 725360 | TENA Flex Ultima Small 3x20pcs, JP        | 7322540897944 |
| 725400 | TENA Flex Ultima XL 3x17p, INT/NEU NSW    | 7322540884838 |
| 725421 | TENA Flex Maxi XL 3x21p, INT              | 7322540118971 |
| 725460 | TENA Flex Ultima Medium 3x20pcs, JP       | 7322540818635 |
| 725548 | TENA FLEX Ultima S 3x20p, INT             | 7322540884814 |
| 725560 | TENA Flex Ultima Large 3x20pcs, JP        | 7322540818659 |
| 726843 | TENA FLEX Ultima M 3x20p, INT             | 7322540614893 |

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| 727505 | TENA Flex Normal Plus L 3x30 INT NEU NSW | 7322541112398 |
| 727506 | TENA FLEX Ultima L 3x20p, INT            | 7322540615418 |
| 727507 | TENA Flex Maxi M 3x22p INT ProSkin       | 7322541320625 |
| 727508 | TENA Flex Maxi L 3x22p INT ProSkin       | 7322541320861 |
| 728001 | TENA Flex Super Plus L 3x22p INT NEU NSW | 7322541112862 |
| 728002 | TENA Flex Super Plus XL 3x21 INT NEU NSW | 7322541112992 |
| 728312 | TENA Flex Maxi XL 3x21p INT ProSkin      | 7322541320847 |
| 728533 | TENA Flex Maxi XL 3x21p INT/NEU NSW      | 7322541405209 |
| 728534 | TENA Flex Ultima XL 3x17p INT/NEU NSW    | 7322541405438 |
| 728599 | TENA Flex Plus L 3x30p INT/NEU NSW       | 7322541405759 |
| 728694 | TENA Flex Plus L 3x30p IT NSW            | 7322541405957 |
| 728695 | TENA Flex Super L 3x30p INT/NEU NSW      | 7322541406077 |
| 728749 | TENA Flex Super L 3x30p IT NSW           | 7322541406169 |
| 729281 | TENA Flex Super L 3x30p INT NSW          | 7322541406077 |
| 729352 | TENA Flex Maxi L 3x22p INT NSW           | 7322541406411 |
| 729620 | TENA Flex Maxi L 3x22p INT/NEU NSW       | 7322541406411 |
| 729695 | TENA Flex Ultima L 3x20p INT NSW         | 7322541406633 |
| 729909 | TENA Flex Ultima L 3x20p INT/NEU NSW     | 7322541406633 |
| 730082 | TENA Flex Normal M 3x34p INT/NEU NSW     | 7322541406886 |
| 730369 | TENA Flex Normal M 3x34p INT NSW         | 7322541406886 |
| 730430 | TENA Flex Plus M 3x30p INT NSW           | 7322541407104 |
| 730431 | TENA Flex Plus M 3x30p INT/NEU NSW       | 7322541407104 |
| 730432 | TENA Flex Plus M 3x30p IT NSW            | 7322541407319 |
| 730433 | TENA Flex Maxi M 3x22p INT/NEU, NSW      | 7322541407432 |
| 730434 | TENA Flex Maxi M 3x22p INT NSW           | 7322541407432 |
| 730435 | TENA Flex Ultima M 3x20p INT NSW         | 7322541407678 |
| 730436 | TENA Flex Ultima M 3x20p INT/NEU NSW     | 7322541407678 |
| 730437 | TENA Flex Plus S 3x30p INT NSW           | 7322541407951 |
| 730438 | TENA Flex Plus S 3x30p INT/NEU NSW       | 7322541407951 |
| 730439 | TENA Flex Plus S 3x30p IT NSW            | 7322541408170 |
| 730440 | TENA Flex Super S 3x30p INT/NEU NSW      | 7322541408644 |
| 730445 | TENA Flex Super S 3x30p IT NSW           | 7322541408552 |
| 730446 | TENA Flex Super S 3x30p INT NSW          | 7322541408644 |
| 730447 | TENA Flex Maxi S 3x22p INT/NEU NSW       | 7322541410449 |
| 730453 | TENA Flex Maxi S 3x22p INT NSW           | 7322541410449 |
| 730454 | TENA Flex Ultima S 3x20p INT NSW         | 7322541410548 |
| 730455 | TENA Flex Ultima S 3x20p INT/NEU NSW     | 7322541410548 |
| 730456 | TENA Flex Super M 3x30p INT/NEU NSW      | 7322541410937 |
| 730457 | TENA Flex Super M 3x30p IT NSW           | 7322541411026 |
| 730458 | TENA Flex Super M 3x30p INT NSW          | 7322541410937 |
| 750506 | TENA Flex Maxi Large Basic               | 7322541230245 |
| 750507 | TENA Flex Super Medium Basic             | 7322541230252 |

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| 750508 | TENA Flex Maxi Large Discreet   | 7322541230269 |
| 750509 | TENA Flex Maxi Medium Discreet  | 7322541230276 |
| 750510 | TENA Flex Super Large Discreet  | 7322541230283 |
| 750511 | TENA Flex Super Medium Discreet | 7322541230290 |
| 750513 | TENA Flex Plus Large Discreet   | 7322541230306 |
| 750514 | TENA Flex Plus Medium Discreet  | 7322541230313 |
| 750516 | TENA Flex Plus Small Discreet   | 7322541230320 |
| 750517 | TENA Flex Normal XL             | 7322541230337 |
| 750518 | TENA Flex Normal S              | 7322541230344 |

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