# EU DECLARATION OF CONFORMITY

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|---|---|
| **Company:** | Essity Hygiene and Health AB<br>SE-405 03 Göteborg<br>Sweden<br>Visitor's address: Mölndals Bro 2, Mölndal, Sweden<br><br>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.<br><br>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<br><br>Romana Stefek<br>Global Regulatory Affairs/Product Safety Director<br>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.

**Essity Hygiene and Health AB**
SE-405 03 GÖTEBORG
Sweden
Visitors' address:Mölndals Bro 2, Mölndal
Phone: *+46 31 746 00 00*
***www.essity.com***

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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