# 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 Bed |
| **Basic UDI-DI:** | 7322540100806S |
| **Medical devices:** | See enclosed list |
| **Risk class:** | Class I |
| **Common Specification:** | N/A |
| **Notified Body:** | N/A, since class I |
| **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:** | 61850 |
| **EMDN code:** | T04010299 |

**Signatory:** Mölndal, on 2022-04-29

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.

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Seat: Göteborgs kommun. Registration number: SE556007-2356



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| Article Number | Article | UDI-DI |
|---|---|---|
| 100387 | TENA Bed Super SecZone 60x90 60x1pcs AB | 7322541278131 |
| 100388 | TENA Bed Super SecZone 60x60 60x1pcs AB | 7322541278223 |
| 100389 | TENA Bed Super 60x90 96x1pcs AB | 7322541278315 |
| 100390 | TENA Bed PlusWing 180x80 SZ 44x1pcs AB | 7322541278421 |
| 100391 | TENA Bed Plus SecureZone 90x80 44x1pcs B | 7322541278490 |
| 100392 | TENA Bed Plus SecZone 60x90 76x1pcs AB | 7322541278599 |
| 100393 | TENA Bed Plus SecureZone 60x75 76x1pcs B | 7322541278698 |
| 100394 | TENA Bed Plus SecZone 60x60 76x1pcs AB | 7322541278780 |
| 100395 | TENA Bed Plus SecZone 60x40 100x1pcs AB | 7322541278896 |
| 100396 | TENA Bed Plus 60x90 112x1pcs AB | 7322541278988 |
| 100397 | TENA Bed Plus 60x60 112x1pcs AB | 7322541279145 |
| 100398 | TENA Bed Plus 60x40 130x1pcs AB | 7322541279244 |
| 100399 | TENA Bed Original 60x90 130x1pcs AB | 7322541279336 |
| 100400 | TENA Bed Original 60x60 130x1pcs AB | 7322541279398 |
| 100401 | TENA Bed Normal 60x90 128x1pcs B | 7322541279527 |
| 100402 | TENA Bed Normal 60x60 128x1pcs B | 7322541279619 |
| 770037 | TENA Bed Normal 60x60 | 7322540525427 |
| 770038 | TENA Bed Normal 60x90 | 7322540529319 |
| 770039 | TENA Bed Normal 60x60 10p | 7322540666861 |
| 770040 | TENA Bed Normal 60x90 10p | 7322540666885 |
| 770044 | TENA Bed Normal 60x60 | 7322540729443 |
| 770045 | TENA Bed Normal 60x60 | 7322540729443 |
| 770046 | TENA Bed Normal 60x90 | 7322540729733 |
| 770047 | TENA Bed Normal 60x90 | 7322540729733 |
| 770048 | TENA Bed Original 60x60 | 7322540736281 |
| 770049 | TENA Bed Original 60x90 | 7322540736304 |
| 770054 | TENA Bed Plus Secure Zone, 60x60, 24x5p, OTC Edition | 7322540538410 |
| 770055 | TENA Bed Plus Secure Zone, 60x90, 24x5p, OTC Edition | 7322540538434 |
| 770056 | TENA Bed Normal 60x60 24x5p | 7322540576405 |
| 770057 | TENA Bed Normal 60x90 24x5p | 7322540576382 |
| 770064 | TENA Bed Plus 60x60, 24x5p, OTC Edition | 7322540801910 |
| 770065 | TENA Bed Plus 60x90, 24x5p, OTC Edition | 7322540801934 |
| 770068 | TENA Bed Normal 60x90 10x10pcs INT | 8699114503532 |
| 770069 | TENA Bed Normal 60x90 5x30pcs INT | 8699114503549 |
| 770071 | TENA Bed Normal 60x90 | 7322540479331 |
| 770073 | TENA Bed Normal 60x90 | 7322540479331 |
| 770077 | TENA Bed Normal 90x180 6x30 pcs INT | 8699114503556 |
| 770078 | RINACARE Underpad 60x90, 5x30pcs | 8699114504423 |
| 770079 | RINACARE Underpad 60x90, 10x10pcs | 8699114504430 |
| 770100 | TENA Bed Plus Secure Zone 60x60, 4x30p | 7322540520811 |



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|---|---|---|
| 770103 | TENA Bed Plus Secure Zone 60x90, 4x20p | 7322540520873 |
| 770104 | TENA Bed Plus Secure Zone 60x90, 4x30p | 7322540520897 |
| 770108 | TENA Bed Plus Secure Zone 90x80, 4x20p N | 7322540520934 |
| 770109 | TENA Bed Plus Secure Zone 60x60, 4x30p N | 7322540520811 |
| 770111 | TENA Bed Plus Secure Zone 60x90, 4x30p N | 7322540520897 |
| 770113 | TENA Bed Plus Secure Zone 60x40, 6x30p | 7322540530469 |
| 770114 | TENA Bed Plus Secure Zone 60x40, 6x30p N | 7322540530469 |
| 770115 | TENA Bed Plus Secure Zone 60x75, 3x30p | 7322540530483 |
| 770118 | TENA Bed Plus 60x40 | 7322540728859 |
| 770119 | TENA Bed Plus 60x60 | 7322540729160 |
| 770120 | TENA Bed Plus 60x90 | 7322540728873 |
| 770121 | TENA Bed Plus 60x75 | 7322540729207 |
| 770124 | TENA Bed Plus 60x60, 4x30p | 7322540800746 |
| 770125 | TENA Bed Plus 60x90, 4x30p | 7322540800760 |
| 770131 | TENA Bed Plus SecureZone 60x75, 4x25pcs N | 7322541189093 |
| 770132 | TENA Bed Plus 60x40, 6x40pcs INT/IT | 7322540728859 |
| 770133 | TENA Bed Plus 60x90, 4x20p INT | 7322541481012 |
| 770202 | TENA Bed Super Secure Zone 60x60, 4x30p | 7322540521061 |
| 770207 | TENA Bed Super Secure Zone 60x60, 4x30p N | 7322540521061 |
| 770208 | TENA Bed Super Secure Zone 60x90, 2x30p N | 7322540521108 |
| 770210 | TENA Bed Super SecureZone 60x90, 3x26p N | 7322541199122 |
| 771102 | TENA Bed PlusWing 180x80 Secure Zone, 4x20p IT | 7322540520958 |
| 771103 | TENA Bed PlusWing 180x80 Secure Zone, 4x20p N | 7322540520958 |
| 772531 | TENA Bed Super 60x75 | 7322540729269 |
| 772532 | TENA Bed Super 60x90 | 7322540742343 |
| 772534 | TENA Bed Super 60x75,  4x28pcs IT | 7322541199030 |



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