

# 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 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.

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.

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                                              | 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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