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 Jun 3, 2024

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.

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

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 09:43 Uhr · sana.swiss

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

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770079	RINACARE Underpad 60x90, 10x10pcs	8699114504430
770100	TENA Bed Plus Secure Zone 60x60, 4x30p	7322540520811
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
771106	TENA Bed PWing 180x80 SZ 4x20 INT/IT NSW	7322542335437
771107	TENA Bed PlusWing 180x80 SZ 4x20 NEU NSW	7322542335727
772531	TENA Bed Super 60x75	7322540729269
772532	TENA Bed Super 60x90	7322540742343
772534	TENA Bed Super 60x75, 4x28pcs IT	7322541199030

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