

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 Comfort

Basic UDI-DI: 7322540100736V

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: T04010102

Signatory: Mölndal, on May 15, 2024



Romana Stefek
 Global Regulatory Affairs Director
 PRRC Medical Devices, Cosmetics/Biocides, Certified Products

* 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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 Sweden
 Visitors' address: Mölndals Bro 2, Mölndal
 Phone: +46 31 746 00 00
www.essity.com

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	6.0

Article number	Article Name	UDI-DI
100174	TENA Comfort Normal Ps 104x1pcs AB	7322541248219
100175	TENA Comfort Plus Ps 52x1pcs AB	7322541248288
100192	TENA Comfort Extra Ps 52x1pcs AB	7322541250182
100193	TENA Comfort Super Ps 52x1pcs AB	7322541250250
100194	TENA Comfort Maxi Ps 36x1pcs AB	7322541250328
100195	TENA Comfort Original Normal 104x1p AB	7322541250618
100196	TENA Comfort Original Plus 52x1pcs AB	7322541250700
100197	TENA Comfort Original Extra 52x1pcs AB	7322541250786
100198	TENA Comfort Ultima Ps 36x1pcs AB	7322541250854
100199	TENA Comfort Original Super 52x1pcs AB	7322541250939
100201	TENA Comfort Original Maxi 36x1pcs AB	7322541251011
100202	TENA Comfort Anatomico N 104x1pcs ES	7322541251097
100203	TENA Comfort Anatomico P 52x1pcs ES	7322541251172
100204	TENA Comfort Anatomico E 52x1pcs ES	7322541251257
100205	TENA Comfort Anatomico S 52x1pcs ES	7322541251349
100501	TENA Comfort Ultima Vinda Ps 48x1p AB	7322541328881
100675	TENA Comfort Maxi Ps 52x1pcs AB	7322541939780
211422	TENA Comfort Original Value Norm 3x42p N	7322540728682
211431	TENA Comfort Original Value Plus 2x46p N	7322541398785
211432	TENA Comfort Original ValueExtra 2x40p N	7322541398808
211433	TENA Comfort Original Value Super 2x36 N	7322541398921
211435	TENA Comfort Original Value Maxi 2x28, N	7322541398945
211436	TENA Comfort Basic Value Plus 3x36 pcs	7322541398969
211437	TENA Comfort Basic Value Extra 3x36pcs	7322541398983
211438	TENA Comfort Basic Value Super 3x36pcs	7322541399003
211439	TENA Comfort Basic Value Maxi 3x28pcs	7322541399027
211441	TENA Comfort Basic Value Normal 3x36p	7322541399041
211471	TENA Comfort Original Normal 3x42 pcs,Neutral	7322540710502
211472	TENA Comfort Original Plus 2x40 pcs, Neutral	7322540734515
211473	TENA Comfort Original Extra 2x40 pcs, Neutral	7322540710717
211474	TENA Comfort Original Super 2x36 pcs, Neutral	7322540710731
211475	TENA Comfort Original Maxi 2x28 pcs, Neutral	7322540710755
211476	TENA Comfort Original Plus 2x46 pcs, Neutral	7322540710694
211518	TENA Comfort Original Maxi 2x34pNeutral	7322541752822
211522	TENA Comfort Original Maxi 2x34p,INT	7322541752822
211526	TENA Comfort Original ValueExtraP 2x40pN	7322541809564
211527	TENA Comfort Original Value Ultima 2x28N	7322541810126
212240	TENA Anatomico Comfort Normal 3x40pcs ES	7322540710649
212244	TENA Comfort Anatomico Normal 2x40 p + Fix pant	7322540834475
212742	TENA Comfort Original Normal 3x42 pcs INT	7322540710502

Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	6.0

212841	TENA Comfort Anatomico Plus 2x40 p + Fix pant	7322540835137
212846	TENA Comfort Original Plus 2x46 pcs INT	7322540710694
212850	TENA Comfort Original Plus 2x40 pcs IT	7322540734515
212940	TENA Comfort Original Extra 2x40 pcs INT	7322540710717
213040	TENA Anatomico Comfort Extra 2x40 pcs ES	7322540710793
213041	TENA Comfort Anatomico Extra 2x40 p + Fix pant	7322540835144
218036	TENA Comfort Original Super 2x36 pcs INT	7322540710731
218541	TENA Comfort Anatomico Super 2x40 p + Fix pant	7322540835151
219028	TENA Comfort Original Maxi 2x28 pcs INT	7322540710755
752742	TENA Comfort Normal 3x42 pcs INT	7322540696011
752744	TENA Comfort Plus Comp 3x42pcs, Neu NSW	7322541798943
752846	TENA Comfort Plus 2x46 pcs INT	7322540696035
752859	TENA Comfort Plus 2x40 pcs IT	7322540736892
752862	TENA Comfort Plus, 2x40 pcs, Neutral	7322542396322
753040	TENA Comfort Extra 2x40 pcs INT	7322540696196
758006	TENA Comfort Maxi, 2x34pcs, Neutral	7322541751900
758007	TENA Comfort Maxi, 2x34pcs, INT/IT	7322541751900
758008	TENA Comfort Maxi, 2x34pcs, Neutral	7322542396421
758136	TENA Comfort Super 2x36 pcs INT	7322540698107
759000	TENA Comfort Normal, 3x42pcs, Neutral	7322540696011
759002	TENA Comfort Extra, 2x40p, Neutral	7322540696196
759003	TENA Comfort Super, 2x36pcs, Neutral	7322540698107
759004	TENA Comfort Maxi, 2x28pcs, Neutral	7322540696219
759005	TENA Comfort Plus, 2x46 pcs, Neutral	7322540696035
759006	TENA Comfort Ultima, 2x26pcs, Neutral	7322541274201
759007	TENA Comfort Normal, 3x42pcs, Neutral	7322541460758
759008	TENA Comfort Plus, 2x46 pcs, Neutral	7322541460871
759009	TENA Comfort Extra, 2x40p, Neutral	7322541461236
759010	TENA Comfort Super, 2x36pcs, Neutral	7322541461038
759011	TENA Comfort Ultima, 2x26pcs, Neutral	7322541461120
759012	TENA Comfort Maxi, 2x28pcs, Neutral	7322541461212
759128	TENA Comfort Maxi 2x28 pcs INT	7322540696219

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PROHLÁŠENÍ O SHODĚ ES

Společnost: Essity Hygiene and Health AB
SE-405 03 Göteborg
Sweden
Adresa: Mölndals Bro 2, Mölndal, Sweden

SRN number: SE-MF-000000004

Produkty: TENA Comfort

Basic UDI-DI: 7322540100736V

Zdravotnický prostředek: Seznam níže
Riziková třída: Třída I

Specifikace: N/A

Notifikovaná osoba: N/A, riziková třída I

Prohlášení: tímto prohlašujeme jako výrobce* zdravotnických prostředků uvedených v seznamu níže, že zdravotnické prostředky splňují příslušná ustanovení Nařízení o zdravotnických prostředcích (EU) 2017/745 (MDR) a splňují veškeré relevantní požadavky na bezpečnost a funkčnost stanovené MDR. Prostředky jsou klasifikované dle přílohy VIII MDR. Toto prohlášení o shodě je vydáno dle výhradní zodpovědnosti výrobce.

Účel použití: Prostředky jsou určeny pro inkontinenční péči.
GMDN kód: 11239
EMDN kód: T04010102

Signatory:

Mölndal, dne 15.5.2024
Romana Stefek
Global Regulatory Affairs/Product Safety Director
PRRC, LM Essity Hygiene and Health AB
** dle definice v nařízení o zdravotnických prostředcích (EU) 2017/745*

Toto prohlášení zůstává v platnosti, dokud není nahrazeno novou verzí.

Essity Hygiene and Health AB
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Švédsko

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