

# EU DECLARATION OF CONFORMITY

Essity Hygiene and Health AB  
SE-405 03 Göteborg  
Sweden  
Visitor's address: Mölndals Bro 2, Mölndal

SRN number: SE-MF-000000004

hereby declares being the manufacturer\* of the medical devices TENA Comfort 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 requirements in MDR.

The devices are intended for incontinence care and are classified in Class I according to Annex VIII in MDR.

The GMDN code is 11239, the EMDN/CND code is T04010102 and the Basic UDI-DI is 7322540100736V.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Mölndal, on January 2021-01-26



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Romana Stefek  
Global Regulatory Affairs/Product Safety Director  
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
Declaration of Conformity	FORM-00733	4.0

Article Number	Article	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
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

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211475	TENA Comfort Original Maxi 2x28 pcs, Neutral	7322540710755
211476	TENA Comfort Original Plus 2x46 pcs, Neutral	7322540710694
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
212840	TENA Anatomico Comfort Plus 2x40 pcs ES	7322540710779
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
218540	TENA Anatomico Comfort Super 2x40 pcs ES	7322540710816
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
752846	TENA Comfort Plus 2x46 pcs INT	7322540696035
752859	TENA Comfort Plus 20x40 pcs IT	7322540736892
753040	TENA Comfort Extra 2x40 pcs INT	7322540696196
758037	TENA Comfort super ES	7322540414592
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
759128	TENA Comfort Maxi 2x28 pcs INT	7322540696219

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