

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Comfort intended for incontinence care according to the enclosed article list, fulfill the provisions of Council Directive 93/42/EEC of 14 June 1993, amended as relevant.

The products are classified as medical devices class I according to said Directive and the GMDN code is 11239.

The conformity assessment is carried out in accordance with Annex VII of the Medical Device Directive 93/42/EC.

The products are hereby also in conformity with all relevant parts of Swedish legislation regarding requirements of the Medical Devices Directive and corresponding regulation from Medical Products Agency. The articles are notified with Swedish competent authority, Medical Products Agency.

Mölnadal, on November 29th, 2019



Romana Stefek
Global Regulatory Affairs/Product Safety Director
LM Essity Hygiene and Health AB

Essity Hygiene and Health AB
405 03 GÖTEBORG
SWEDEN

We are Essity - formerly SCA Hygiene
Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Sweden

This Declaration of Conformity is valid until replaced with a new version and no longer than May 25th, 2020. It is managed by SCR GBIS Certified Products Department - Hygiene

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Seat: Göteborgs kommun. Registration number: SE556007-2356

Product Name	Product No.	Version	Page
Essity Hygiene and Health AB	PT 15152	0.0	1/1

TENA Comfort Assortment

Article number	Article
211422	TENA Comfort Original Value Norm 3x42p N
211431	TENA Comfort Original Value Plus 2x46p N
211432	TENA Comfort Original ValueExtra 2x40p N
211433	TENA Comfort Original Value Super 2x36 N
211435	TENA Comfort Original Value Maxi 2x28, N
211436	TENA Comfort Basic Value Plus 3x36 pcs
211437	TENA Comfort Basic Value Extra 3x36pcs
211438	TENA Comfort Basic Value Super 3x36pcs
211439	TENA Comfort Basic Value Maxi 3x28pcs
211441	TENA Comfort Basic Value Normal 3x36p
211471	TENA Comfort Original Normal 3x42 pcs, Neutral
211472	TENA Comfort Original Plus 2x40 pcs, Neutral
211473	TENA Comfort Original Extra 2x40 pcs, Neutral
211474	TENA Comfort Original Super 2x36 pcs, Neutral
211475	TENA Comfort Original Maxi 2x28 pcs, Neutral
211476	TENA Comfort Original Plus 2x46 pcs, Neutral
212240	TENA Anatomico Comfort Normal 3x40pcs ES
212244	TENA Comfort Anatomico Normal 2x40 p + Fix pant
212742	TENA Comfort Original Normal 3x42 pcs INT
212840	TENA Anatomico Comfort Plus 2x40 pcs ES
212841	TENA Comfort Anatomico Plus 2x40 p + Fix pant
212846	TENA Comfort Original Plus 2x46 pcs INT
212850	TENA Comfort Original Plus 2x40 pcs IT
212940	TENA Comfort Original Extra 2x40 pcs INT
213040	TENA Anatomico Comfort Extra 2x40 pcs ES
213041	TENA Comfort Anatomico Extra 2x40 p + Fix pant
218036	TENA Comfort Original Super 2x36 pcs INT
218540	TENA Anatomico Comfort Super 2x40 pcs ES
218541	TENA Comfort Anatomico Super 2x40 p + Fix pant
219028	TENA Comfort Original Maxi 2x28 pcs INT
752742	TENA Comfort Normal 3x42 pcs INT
752846	TENA Comfort Plus 2x46 pcs INT
752859	TENA Comfort Plus 2x40 pcs IT
753001	TENA Comfort Extra 8x10pcs
753040	TENA Comfort Extra 2x40 pcs INT
758037	TENA Comfort super ES
758136	TENA Comfort Super 2x36 pcs INT
759000	TENA Comfort Normal, 3x42pcs, Neutral
759002	TENA Comfort Extra, 2x40p, Neutral
759003	TENA Comfort Super, 2x36pcs, Neutral
759004	TENA Comfort Maxi, 2x28pcs, Neutral
759005	TENA Comfort Plus, 2x46 pcs, Neutral
759128	TENA Comfort Maxi 2x28 pcs INT

