

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Men 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

Seat: Göteborgs kommun. Registration number: SE556007-2356

Visitors' address:
Mölnäls Bro 2, Mölnadal
Phone: +46 31 746 00 00
www.essity.com

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TENA Men Assortment

Article number	Article
50600	TENA Men, level 2
50701	TENA Men Prot Guards Level 2 6x10p
50730	TENA Men Absorbent Shields, 8x14p, CA
50751	TENA Men Absorbent Guards, 6x20p, MX
52700	TENA Men Absorbent Guards, 3x48p, CA
54196	TENA Men Absorbent Guards, 3x20p, US
54197	TENA Men Absorbent Guards, 3x48p, US
750403	TENA Men Protective Shield Extra Light, 8x14p
750404	TENA Men Protective Shield, 3x14p
750406	TENA Men Protective Shield, 8x14p
750449	TENA Men Protective Shield Extra Light, 8x14p
750459	TENA Men Protective Shield, Level 0, 8x14p, East
750463	TENA Men Protective Shield, Level 0, 8x14p, eC
750651	TENA Men Level 1 Light, 6x24p
750652	TENA Men Level 1 Light, 6x24p
750653	TENA Men Level 1 Light, 6x24p
750654	TENA Men Level 1 Light, 6x24p
750658	TENA Men Level 1 Light, 4x12p
750661	TENA Men Level 1 Light, 8x12p
750662	TENA Men Level 1 Light, 8x12p
750663	TENA Men Level 1 Light, 8x12p
750677	TENA MEN Light Level 1, 6x24p, ES/PT
750700	TENA MEN Medium Level 2, 2x10p, SRP
750759	TENA Men Level 2 Medium, 4x10p
750776	TENA Men Level 2 Medium, 6x20p
750784	TENA Men Level 2 Medium, 6x20p
750789	TENA Men Level 2 Medium, 6x20p
750795	TENA Men Level 2 Medium, 6x20p
750796	TENA Men Level 2 Medium, 6x10p
750797	TENA Men Level 2 Medium, 3x10p
750798	TENA Men Level 2 Medium, 6x10p
750800	TENA Men Level 2 Medium, 6x10p
750809	TENA MEN Medium Level 2, 6x10p, eC
750829	TENA MEN Medium Level 2, 6x20p, ES/PT
750830	TENA Men Level 3 Super, 6x16p
750833	TENA Men Level 3 Super, 6x16p
750834	TENA Men Level 3 Super, 6x16p
750835	TENA Men Level 3 Super, 6x16p
750836	TENA Men Level 3 Super, 3x8p
750855	TENA Men Level 3 Super, 6x8p
750856	TENA Men Level 3 Super, 6x8p
750858	TENA Men Level 3 Super, 6x20p
750860	TENA Men Super Level 3, 6x16p, ES/PT
750863	TENA Men Super Level 3, 6x8p, FR
750865	TENA MEN Medium Level 2, 8x10p, FR