

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Pants Bariatric 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 41588.

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.

Article number	Article
792862	TENA Pants Bariatric Plus XXL, 4x12 pcs

Mölnådal, on December 13th, 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
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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

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