



EU Declaration of Conformity according to MDR

Title: Basic Scrub Suits and Warm Up Jackets, BNS

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Basic Scrub Suits and Warm Up Jacket, BNS
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Product Classification: MDR Class I ns

MDR Classification Rule: 1

Sterility: Non-sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IV
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Common Specification: No CS is applicable

Certificate number:	Not Applicable
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Issued by:	Not Applicable
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Id No:

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2024-02-12

Function:

Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:



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Generic product information	
Intended Purpose:	Scrub Apparels, used by staff as working clothes, are intended to protect the patient from the staff's own bacterial flora by providing a barrier.
Basic UDI-DI:	733243000000000099KM
GMDN Code:	58382 Scrub suit, single-use, non-sterile
EMDN Code:	T0209 PROTECTION DRAPES AND GARMENTS - OTHER

Product References Covered by this Declaration:	Product	Product Descriptor:
831010	Warm-Up Jacket, S, Blue	WARM-UP JACKET
831020	Warm-Up Jacket, M, Blue	WARM-UP JACKET
831030	Warm-up Jacket, L, Blue	WARM-UP JACKET
831040	Warm-up Jacket, XL, Blue	WARM-UP JACKET
832009	Basic Scrub-suit, XS, Purple	SCRUB SUIT
832010	Warm-Up Jacket, S, Green	WARM-UP JACKET
832020	Warm-Up Jacket, M, Green	WARM-UP JACKET
832030	Warm-Up Jacket, L, Green	WARM-UP JACKET
832040	Warm-Up Jacket, XL, Green	WARM-UP JACKET
832109	Basic Scrub suit, S, Purple	SCRUB SUIT
832209	Basic Scrub suit, M, Purple	SCRUB SUIT
832309	Basic Scrub suit, L, Purple	SCRUB SUIT
832409	Basic Scrub suit, XL, Purple	SCRUB SUIT
832509	Basic Scrub-suit, XXL, Purple	SCRUB SUIT
836009	Basic Scrub suit, XS, Blue	SCRUB SUIT
836109	Scrub Suit, Blue, S	SCRUB SUIT
836209	Scrub Suit, Blue, M	SCRUB SUIT
836309	Scrub Suit, Blue, L	SCRUB SUIT
836409	Scrub Suit, Blue, XL	SCRUB SUIT



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Title: Basic Scrub Suits and Warm Up Jackets, BNS

836509	Basic Scrub suit, XXL, Blue	SCRUB SUIT
839105	Basic Scrub Shirt , XS, Green	SCRUB SHIRT
839109	SCRUB SHIRT, S, green	SCRUB SHIRT
839209	SCRUB SHIRT, M, green	SCRUB SHIRT
839309	SCRUB SHIRT, L, green	SCRUB SHIRT
839409	SCRUB SHIRT, XL, green	SCRUB SHIRT
839459	Basic Scrub shirt, XXL, Green	SCRUB SHIRT
839505	Basic Drawstring pants, XS, Green	DRAWSTRING PANTS
839509	DRAWSTRING PANTS, S, green	DRAWSTRING PANTS
839609	DRAWSTRING PANTS, M, green	DRAWSTRING PANTS
839709	DRAWSTRING PANTS, L, green	DRAWSTRING PANTS
839809	DRAWSTRING PANTS, XL, green	DRAWSTRING PANTS
839859	Basic Drawstring pants, XXL, Green	DRAWSTRING PANTS