



**EU Declaration of Conformity
according to MDR**

Document ID: PD-608125 Rev: 00
Created by: Zahrah Chaudhary
Approved by: Christina Lewing
Approval date: 2021-03-23

Title: Basic scrub suits and warm up jackets

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We, Mölnlycke Health Care, Gamlestadvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden 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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: **Not applicable**

Trade name/ Product name:	Basic scrub suits and warm up jackets
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Product classification: **I**
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
Common Specification:	No CS is applicable

Certificate number:	Not Applicable
Issued by:	Not Applicable
NB. For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	

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

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: **2021-03-23** Function: **Regulatory Affairs Director**

Name: **Christina Lewing**

Signature:

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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.

Product(s) covered by this declaration:

Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
831010	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
831020	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
831030	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
831040	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832009	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832010	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832020	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832030	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832040	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832109	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832209	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832309	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
832409	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
832509	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836009	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836109	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836209	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836309	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836409	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
836509	SCRUB SUIT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839105	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839109	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839209	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839309	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839409	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839459	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839505	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
839509	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
839609	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
839709	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
839809	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
839859	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile