



EU Declaration of Conformity according to MDR

Document ID: PD-605567 **Rev:**01
Created by: Gayle Wood
State: Released
Approved by: Christina Lewing
Approval date: 2023-07-04 09:11:41
Release date: 2023-07-04 09:11:49

Title: Extra Comfort Scrub Suits and Warm Up Jackets

Dates and times in Greenwich Mean Time, 24 hours format

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:	Extra Comfort Scrub Suits and Warm Up Jackets
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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: 2023-07-04

Function: Global Regulatory Affairs Director

Name: Christina Lewing

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

Product References Covered by this Declaration:	Product Descriptor:
18001	WARM-UP JACKET
18010	WARM-UP JACKET
18020	WARM-UP JACKET
18030	WARM-UP JACKET
18040	WARM-UP JACKET
18050	WARM-UP JACKET
18200	XP WARM-UP JACKET
18210	XP WARM-UP JACKET
18220	XP WARM-UP JACKET
18230	XP WARM-UP JACKET
18240	XP WARM-UP JACKET
18250	XP WARM-UP JACKET
18300	WARM-UP JACKET, MEDIUM SLEEVE
18310	WARM-UP JACKET, MEDIUM SLEEVE
18320	WARM-UP JACKET, MEDIUM SLEEVE
18330	WARM-UP JACKET, MEDIUM SLEEVE
18340	WARM-UP JACKET, MEDIUM SLEEVE
18600	SCRUB SHIRT
18610	SCRUB SHIRT
18620	SCRUB SHIRT



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18630	SCRUB SHIRT
18640	SCRUB SHIRT
18650	SCRUB SHIRT
18660	SCRUB SHIRT
18670	SCRUB SHIRT
18700	DRAWSTRING PANTS
18710	DRAWSTRING PANTS
18720	DRAWSTRING PANTS
18730	DRAWSTRING PANTS
18740	DRAWSTRING PANTS
18750	DRAWSTRING PANTS
18760	DRAWSTRING PANTS
18770	DRAWSTRING PANTS
18920	WOMENS ELASTIC WAIST SLACKS
18930	WOMENS ELASTIC WAIST SLACKS
18940	WOMENS ELASTIC WAIST SLACKS
18950	WOMENS ELASTIC WAIST SLACKS
18960	WOMENS ELASTIC WAIST SLACKS
20720	DRAWSTRING PANTS
20730	DRAWSTRING PANTS
20740	DRAWSTRING PANTS
20930	WOMENS ELASTIC WAIST SLACKS
20940	WOMENS ELASTIC WAIST SLACKS
21600	SCRUB SHIRT
21610	SCRUB SHIRT
21620	SCRUB SHIRT
21630	SCRUB SHIRT



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21640	SCRUB SHIRT
21650	SCRUB SHIRT
21660	SCRUB SHIRT
21670	SCRUB SHIRT
21700	DRAWSTRING PANTS
21710	DRAWSTRING PANTS
21720	DRAWSTRING PANTS
21730	DRAWSTRING PANTS
21740	DRAWSTRING PANTS
21750	DRAWSTRING PANTS
21760	DRAWSTRING PANTS
21770	DRAWSTRING PANTS
22300	WARM-UP JACKET, MEDIUM SLEEVE
22310	WARM-UP JACKET, MEDIUM SLEEVE
22320	WARM-UP JACKET, MEDIUM SLEEVE
22330	WARM-UP JACKET, MEDIUM SLEEVE
22340	WARM-UP JACKET, MEDIUM SLEEVE
22600	SCRUB SHIRT
22610	SCRUB SHIRT
22620	SCRUB SHIRT
22630	SCRUB SHIRT
22640	SCRUB SHIRT
22700	DRAWSTRING PANTS
22710	DRAWSTRING PANTS
22720	DRAWSTRING PANTS
22730	DRAWSTRING PANTS
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24000	WARM-UP JACKET
24010	WARM-UP JACKET
24020	WARM-UP JACKET
24030	WARM-UP JACKET
24040	WARM-UP JACKET
24050	WARM-UP JACKET
24600	SCRUB SHIRT
24610	SCRUB SHIRT
24620	SCRUB SHIRT
24630	SCRUB SHIRT
24640	SCRUB SHIRT
24650	SCRUB SHIRT
24660	SCRUB SHIRT
24670	SCRUB SHIRT
24700	DRAWSTRING PANTS
24710	DRAWSTRING PANTS
24720	DRAWSTRING PANTS
24730	DRAWSTRING PANTS
24740	DRAWSTRING PANTS
24750	DRAWSTRING PANTS
24760	DRAWSTRING PANTS
24770	DRAWSTRING PANTS
25300	WARM-UP JACKET, MEDIUM SLEEVE
25310	WARM-UP JACKET, MEDIUM SLEEVE
25320	WARM-UP JACKET, MEDIUM SLEEVE
25330	WARM-UP JACKET, MEDIUM SLEEVE
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28000	WARM-UP JACKET
28010	WARM-UP JACKET
28020	WARM-UP JACKET
28030	WARM-UP JACKET
28040	WARM-UP JACKET
28050	WARM-UP JACKET