



**EU Declaration of Conformity
according to MDR**

Document ID: PD-605567 Rev: 00
Created by: Zahrah Chaudhary
Approved by: Christina Lewing
Approval date: 2021-02-05

Title: Extra Comfort 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:	Extra Comfort 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: **2021-02-05** 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:
18001	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18010	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18020	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18030	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18040	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18050	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18200	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18210	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18220	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18230	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18240	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18250	XP WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
18300	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18310	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18320	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18330	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18340	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18600	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18610	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18620	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18630	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18640	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18650	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18660	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18670	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18700	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18710	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18720	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
18730	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18740	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18750	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18760	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18770	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18920	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18930	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18940	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18950	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
18960	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
20720	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
20730	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
20740	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
20930	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
20940	WOMENS ELASTIC WAIST SLACKS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
21600	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
21610	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21620	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21630	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21640	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21650	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21660	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21670	SCRUB SHIRT	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21700	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21710	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21720	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21730	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21740	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21750	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21760	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
21770	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
22300	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
22310	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22320	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22330	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22340	WARM-UP JACKET, MEDIUM SLEEVE	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22600	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22610	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22620	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22630	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22640	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22700	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22710	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22720	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22730	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
22740	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24000	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24010	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
24020	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24030	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24040	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24050	WARM-UP JACKET	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24600	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24610	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24620	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24630	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24640	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24650	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24660	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24670	SCRUB SHIRT	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24700	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24710	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24720	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile
24730	DRAWSTRING PANTS	73324300000000099KM	58382 Scrub suit, single-use, non-sterile



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Product Reference:	Product Descriptor:	Basic UDI-DI:	GMDN Code:
24740	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
24750	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
24760	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
24770	DRAWSTRING PANTS	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
25300	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
25310	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
25320	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
25330	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
25340	WARM-UP JACKET, MEDIUM SLEEVE	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28000	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28010	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28020	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28030	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28040	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile
28050	WARM-UP JACKET	733243000000000099KM	58382 Scrub suit, single-use, non-sterile