



# EU Declaration of Conformity according to MDR

**Title:** Extra Comfort Scrub Suits and Warm Up Jackets

We, Mölnlycke Health Care AB, Gamlestadvägen 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
Common Specification: No CS is applicable

Certificate number:	Not Applicable	
Issued by:	Not Applicable	Id No:
	<i>(Notified Body Name)</i>	
<i>NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.</i>		

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:	2024-02-23	Function:	Regulatory Affairs Excellence Manager
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Name:	Karin Darle Olsson	Signature:	
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**Title:** Extra Comfort Scrub Suits and Warm Up Jackets

Generic product information	
<b>Intended Purpose:</b>	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.
<b>Basic UDI-DI:</b>	733243000000000099KM
<b>GMDN Code:</b>	58382 Scrub suit, single-use, non-sterile
<b>EMDN Code:</b>	T0209 PROTECTION DRAPES AND GARMENTS - OTHER

Product References Covered by this Declaration:	Product	Product Descriptor:
18001	Warm up jacket, Small, green	WARM-UP JACKET
18010	Warm up jacket, Medium, green	WARM-UP JACKET
18020	Warm up jacket, Large, green	WARM-UP JACKET
18030	Warm up jacket, X-Large, green	WARM-UP JACKET
18040	Warm up jacket, XX-Large, green.	WARM-UP JACKET
18050	Warm up jacket, XXX-Large, green.	WARM-UP JACKET
18300	Warm-Up Jacket, Medium sleeve, Small, Green.	WARM-UP JACKET, MEDIUM SLEEVE
18310	Warm-Up Jacket, Medium sleeve, Medium, Green.	WARM-UP JACKET, MEDIUM SLEEVE
18320	Warm-Up Jacket, Medium sleeve, Large, Green.	WARM-UP JACKET, MEDIUM SLEEVE
18330	Warm-Up Jacket, Medium sleeve, X-Large, Green.	WARM-UP JACKET, MEDIUM SLEEVE
18340	Warm-Up Jacket, Medium sleeve, XX-Large, Green.	WARM-UP JACKET, MEDIUM SLEEVE
18600	Scrub-shirt, X-Small, green	SCRUB SHIRT
18610	Scrub-shirt, Small, green	SCRUB SHIRT



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**Title:** Extra Comfort Scrub Suits and Warm Up Jackets

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18620	Scrub-shirt, Medium, green	SCRUB SHIRT
18630	Scrub-shirt, Large, green	SCRUB SHIRT
18640	Scrub-shirt, X-Large, green	SCRUB SHIRT
18650	Scrub-shirt, XX-Large, green	SCRUB SHIRT
18660	Scrub-shirt, XXX-Large, green	SCRUB SHIRT
18670	Scrub-shirt, XXXX-Large, green	SCRUB SHIRT
18700	Drawstring pants, X-Small, green.	DRAWSTRING PANTS
18710	Drawstring pants, Small, green.	DRAWSTRING PANTS
18720	Drawstring pants, Medium, green.	DRAWSTRING PANTS
18730	Drawstring pants, Large, green.	DRAWSTRING PANTS
18740	Drawstring pants, X-Large, green.	DRAWSTRING PANTS
18750	Drawstring pants, XX-Large, green.	DRAWSTRING PANTS
18760	Drawstring pants, XXX-Large, green.	DRAWSTRING PANTS
18770	Drawstring pants, XXXX-Large, green.	DRAWSTRING PANTS
18920	Women´s elastic waist slacks, S.	WOMENS ELASTIC WAIST SLACKS
18930	Women´s elastic waist slacks, M.	WOMENS ELASTIC WAIST SLACKS
18940	Women´s elastic waist slacks, L.	WOMENS ELASTIC WAIST SLACKS
18950	Women´s elastic waist slacks, XL.	WOMENS ELASTIC WAIST SLACKS
18960	Women´s elastic waist slacks, XXL.	WOMENS ELASTIC WAIST SLACKS



## EU Declaration of Conformity according to MDR

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20720	Drawstring pants, Medium	DRAWSTRING PANTS
20730	Drawstring pants, Large	DRAWSTRING PANTS
20740	Drawstring pants, X-Large.	DRAWSTRING PANTS
20930	Women's elastic waist slacks, M	WOMENS ELASTIC WAIST SLACKS
20940	Women's elastic waist slacks, L.	WOMENS ELASTIC WAIST SLACKS
21600	Scrub-shirt, X-Small, blue	SCRUB SHIRT
21610	Scrub-shirt, Small, blue	SCRUB SHIRT
21620	Scrub-shirt, Medium, blue	SCRUB SHIRT
21630	Scrub-shirt, Large, blue	SCRUB SHIRT
21640	Scrub-shirt, X-Large, blue	SCRUB SHIRT
21650	Scrub-shirt, XX-Large, blue	SCRUB SHIRT
21660	Scrub-shirt, XXX-Large, blue	SCRUB SHIRT
21670	Scrub-shirt, XXXX-Large, blue	SCRUB SHIRT
21700	Drawstring pants, X-Small, blue	DRAWSTRING PANTS
21710	Drawstring pants, Small, blue	DRAWSTRING PANTS
21720	Drawstring pants, Medium, blue	DRAWSTRING PANTS
21730	Drawstring pants, Large, blue	DRAWSTRING PANTS
21740	Drawstring pants, X-Large, blue	DRAWSTRING PANTS
21750	Drawstring pants, XX-Large, blue	DRAWSTRING PANTS
21760	Drawstring pants, XXX-Large, blue	DRAWSTRING PANTS
21770	Drawstring pants, XXXX-Large, blue	DRAWSTRING PANTS
22300	Warm-Up Jacket, Medium sleeve, Small, Purple.	WARM-UP JACKET, MEDIUM SLEEVE



## EU Declaration of Conformity according to MDR

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22310	Warm-Up Jacket, Medium sleeve, Medium, Purple.	WARM-UP JACKET, MEDIUM SLEEVE
22320	Warm-Up Jacket, Medium sleeve, Large, Purple.	WARM-UP JACKET, MEDIUM SLEEVE
22330	Warm-Up Jacket, Medium sleeve, X-Large, Purple.	WARM-UP JACKET, MEDIUM SLEEVE
22340	Warm-Up Jacket, Medium sleeve, XX-Large, Purple.	WARM-UP JACKET, MEDIUM SLEEVE
22600	Scrub shirt, XS, green, with cuffs in sleeves and hem	SCRUB SHIRT
22610	Scrub shirt, S, green, with cuffs in sleeves and hem	SCRUB SHIRT
22620	Scrub shirt, M, green, with cuffs in sleeves and hem	SCRUB SHIRT
22630	Scrub shirt, L, green, with cuffs in sleeves and hem	SCRUB SHIRT
22640	Scrub shirt, XL, green, with cuffs in sleeves and hem	SCRUB SHIRT
22700	Drawstring pants, XS, green, with cuff	DRAWSTRING PANTS
22710	Drawstring pants, S, green, with cuff	DRAWSTRING PANTS
22720	Drawstring pants, M, green, with cuff	DRAWSTRING PANTS
22730	Drawstring pants, L, green, with cuff	DRAWSTRING PANTS
22740	Drawstring pants, XL, green, with cuff	DRAWSTRING PANTS
24000	Warm-Up Jacket, long sleeve, Small, Purple.	WARM-UP JACKET
24010	Warm-Up Jacket, long sleeve, Medium, Purple.	WARM-UP JACKET
24020	Warm-Up Jacket, long sleeve, Large, Purple.	WARM-UP JACKET
24030	Warm-Up Jacket, long sleeve, X-Large, Purple.	WARM-UP JACKET



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24040	Warm-Up Jacket, long sleeve, XX-Large, Purple.	WARM-UP JACKET
24050	Warm-Up Jacket, long sleeve, XXX-Large, Purple.	WARM-UP JACKET
24600	Scrub-shirt, X-Small, Purple.	SCRUB SHIRT
24610	Scrub-shirt, Small, Purple.	SCRUB SHIRT
24620	Scrub-shirt, Medium, Purple.	SCRUB SHIRT
24630	Scrub-shirt, Large, Purple.	SCRUB SHIRT
24640	Scrub-shirt, X-Large, Purple.	SCRUB SHIRT
24650	Scrub-shirt, XX-Large, Purple.	SCRUB SHIRT
24660	Scrub-shirt, XXX-Large, Purple.	SCRUB SHIRT
24670	Scrub-shirt, XXXX-Large, Purple.	SCRUB SHIRT
24700	Drawstring pants, X-Small, Purple.	DRAWSTRING PANTS
24710	Drawstring pants, Small, Purple.	DRAWSTRING PANTS
24720	Drawstring pants, Medium, Purple.	DRAWSTRING PANTS
24730	Drawstring pants, Large, Purple.	DRAWSTRING PANTS
24740	Drawstring pants, X-Large, Purple.	DRAWSTRING PANTS
24750	Drawstring pants, XX-Large, Purple.	DRAWSTRING PANTS
24760	Drawstring pants, XXX-Large, Purple.	DRAWSTRING PANTS
24770	Drawstring pants, XXXX-Large, Purple.	DRAWSTRING PANTS
25300	Warm-Up Jacket, medium sleeve, Small, White	WARM-UP JACKET, MEDIUM SLEEVE



## EU Declaration of Conformity according to MDR

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25310	Warm-Up Jacket, medium sleeve, Medium, White	WARM-UP JACKET, MEDIUM SLEEVE
25320	Warm-Up Jacket, medium sleeve, Large, White	WARM-UP JACKET, MEDIUM SLEEVE
25330	Warm-Up Jacket, medium sleeve, X-Large, White	WARM-UP JACKET, MEDIUM SLEEVE
25340	Warm-Up Jacket, medium sleeve, XX-Large, White	WARM-UP JACKET, MEDIUM SLEEVE
28000	Warm up jacket, Small, blue	WARM-UP JACKET
28010	Warm up jacket, Medium, blue	WARM-UP JACKET
28020	Warm up jacket, Large, blue	WARM-UP JACKET
28030	Warm up jacket, X-Large, blue	WARM-UP JACKET
28040	Warm up jacket, XX-Large, blue	WARM-UP JACKET
28050	Warm up jacket, XXX-Large, blue	WARM-UP JACKET