

We, Mölnlycke Health Care AB, 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 the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade name/ Product name:	<b>Extra Comfort Scrub Suits and warm up jackets</b>
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Product classification: **I**Sterility Status: **Non-sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
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Annex/es:	<b>VII</b>
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Certificate number:	<b>Not Applicable</b>
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Issued by:	<b>Not Applicable</b>
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For non sterile, non-measuring Class I products, no certificate is issued by a Notified Body.	
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Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-05-06**Function: **Regulatory Affairs Manager  
Compliance**Name: **Karin Darle Olsson**

Signature:



**Product(s) covered by this declaration:**

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
18001	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18010	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18020	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18030	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18040	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18050	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18200	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18210	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18220	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18230	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
18240	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18250	XP WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
18300	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
18310	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
18320	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
18330	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
18340	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
18600	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18610	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18620	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18630	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
18640	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18650	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18660	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18670	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
18700	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18710	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18720	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18730	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18740	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18750	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18760	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
18770	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
18920	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
18930	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
18940	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
18950	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
18960	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
20720	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
20730	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
20740	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
20930	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile
20940	WOMENS ELASTIC WAIST SLACKS	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
21600	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21610	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21620	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21630	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21640	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21650	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21660	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21670	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
21700	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21710	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21720	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
21730	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21740	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21750	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21760	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
21770	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
22300	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
22310	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
22320	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
22330	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
22340	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
22600	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
22610	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
22620	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
22630	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
22640	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
22700	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
22710	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
22720	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
22730	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
22740	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24000	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
24010	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile



<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
24020	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
24030	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
24040	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
24050	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
24600	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24610	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24620	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24630	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24640	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24650	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24660	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
24670	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
24700	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24710	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24720	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24730	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24740	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24750	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24760	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
24770	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
25300	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
25310	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile

<b>Product Reference:</b>	<b>Product Descriptor:</b>	<b>GMDN Code:</b>
25320	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
25330	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
25340	WARM-UP JACKET, MEDIUM SLEEVE	58382 Scrub suit, single-use, non-sterile
28000	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
28010	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
28020	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
28030	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
28040	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile
28050	WARM-UP JACKET	58382 Scrub suit, single-use, non-sterile