

We, Mölnlycke Health Care AB, Gamlestadsvägen 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:	Basic scrub suits and warm up jackets
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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 Annex/es: VII	
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Certificate number:	Not Applicable
Issued by:	Not Applicable
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 all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: **2020-04-30** Function: **Regulatory Affairs Manager Compliance**

Name: **Karin Darle Olsson**

Signature:



Product(s) covered by this declaration:

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

Product Reference:	Product Descriptor:	GMDN Code:
832209	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
832309	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
832409	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
832509	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836009	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836109	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836209	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836309	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836409	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
836509	SCRUB SUIT	58382 Scrub suit, single-use, non-sterile
839105	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile

Product Reference:	Product Descriptor:	GMDN Code:
839109	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
839209	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
839309	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
839409	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
839459	SCRUB SHIRT	58382 Scrub suit, single-use, non-sterile
839505	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
839509	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
839609	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
839709	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
839809	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile
839859	DRAWSTRING PANTS	58382 Scrub suit, single-use, non-sterile