

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:	<b>Clean Air Suits</b>
------------------------------	------------------------

Product classification: **I**Sterility Status: **Non-sterile**Measuring function: **No**

This declaration is supported by a conformity assessment procedure in accordance with	
---	--

Annex/es:	<b>VII</b>
-----------	------------

Certificate number:	<b>Not Applicable</b>
---------------------	-----------------------

Issued by:	<b>Not Applicable</b>
------------	-----------------------

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: **2020-05-04**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>
842000	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842100	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842200	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842300	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842400	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842500	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
842600	CLEAN AIR SUIT SHIRT	58415 Sealing-cuff scrub suit
843000	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843100	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843200	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843300	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843400	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843500	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit
843600	CLEAN AIR SUIT TROUSERS	58415 Sealing-cuff scrub suit