



**EU Declaration of Conformity
according to MDR**

Document ID: PD-603000 Rev:01
Created by: Zahrah Chaudhary
State: Released
Approved by: Christina Lewing
Release date: 2021-11-02 14:18:37

Title: Clean Air Suits

Dates and times in Greenwich Mean Time, 24 hours format

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 Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Clean Air Suits
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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>Note. For non-sterile, non-measuring class I products there is no Notified Body certificate</i>		

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Place of Issue: Göteborg, Sweden

Date: 2021-11-02 Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	A Clean Air Suit, used as a working garment, is intended to contribute to infection control by reducing contamination of the operating room air from skin scales and bacteria carrying particles originating from the skin of person wearing it.
Basic UDI-DI:	733243000000000098KK
GMDN Code:	58415 Sealing-cuff scrub suit

Product References Covered by this Declaration:	Product Descriptor:
842000	Clean air suit shirt
842100	Clean air suit shirt
842200	Clean Air Suit Shirt
842300	Clean air suit shirt
842400	Clean air suit shirt
842500	Clean air suit shirt
842600	Clean air suit shirt
843000	Clean air suit trousers
843100	Clean air suit trousers
843200	Clean air suit trousers
843300	Clean air suit trousers
843400	Clean air suit trousers
843500	Clean air suit trousers
843600	Clean air suit trousers