

Declaration of Conformity for Scrub Suit SS101X and Scrub Suit SS201X

The device is in conformity with Medical Device regulation 2017/745

	Information
Name and address of Manufacturer	QA MED Solutions ApS Strandvejen 14, 1 DK 5500 Middelfart
SRN-Number	DK-MF-000001649
Basic UDI-DI	574400129-SS101X-5A
Product name/Trade name	Scrub Suit SS101X and Scrub Suit SS201X
Risk class	Class I Medical Device – Rule I Annex VIII of MDR 2017/745
Intended Use	Protective Device for Medical practitioners and patients from cross contamination.
Reference to standards if applicable	EN 13795-1:2019
Notified body name and number (if relevant)	Class I Medical Device. Self-declaration, therefore, no Notified Body

This EU Declaration of Conformity is issued under the sole responsibility of:

QA MED Solutions ApS, Strandvejen 14, 1, DK-5500 Middelfart

Place, date: Middelfart, 2024-09-16

Signed on behalf of QA MED Solution ApS

signature:



Name: Rikke Nygaard

Position: Senior Consultant/ Owner.

Technical file – Scrub Suit

Declaration of Conformity TF-SS101X/SS201X-14

Basic UDI-DI: 574400129-SS101X-5A

Revision + Date	Change	Responsible
2024.08.01 Version 4.1	Layout edited	Silje Merrild Nygaard (SMN)
2024.09.16 Version 5.0	Updated	SMN

