Declaration of Conformity TF-WJ101_WJ201-14
Basic UDI-DI: 574400129-WJ101-4W

Declaration of Conformity for Warm Up Jacket WJ101 and Warm Up Jacket WJ201

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-WJ101-4W
Product name/Trade name	WJ101/PP Warm Up Jacket Dark Blue 47gsm WJ201/SMS Warm Up Jacket Purple 45 gsm
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.

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

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