

Declaration of Conformity for Thermo Mini Poncho MP101

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-MP101-2S
Product name/Trade name	Thermo Mini Poncho 47 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, 2024-09-25

Signed on behalf of QA MED Solution ApS

signature:



Name: Rikke Nygaard

Position: Senior Consultant/ Owner.

Technical file –Thermo Mini Poncho

Declaration of Conformity TF-MP101-14

Basic UDI-DI: 574400129-MP101-2S

Revision + Date	Change	Responsible
2021-05-27 Version 2.1	Edited	Jutta Elia Kaiser (JEK)
2024.08.01 Version 2.2	Layout edited	Silje Merrild Nygaard (SMN)
2024.09.16 Version 3	Updated	SMN
2024.09.25 Version 3 1	Typo updated	SMN



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