

EC - Declaration of Conformity

Manufacturer:

SparMED ApS/CVR. No.: 30898575
Ryttermarken 2, 3520, Denmark

To whom it may concern,

SparMED ApS Denmark, hereby declares under its own responsibility that the products listed below:

- complies with the requirements for clean room workware of American Federal Standard 209, clean room class 10.000-100.000;
- are suitable for IVF laboratory use.

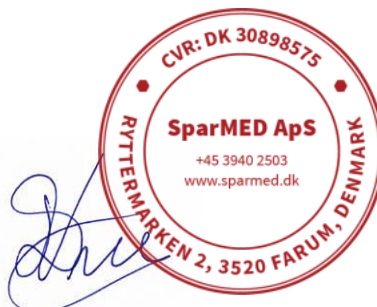
Material conformity was demonstrated by the following Standards.

Test	Standard
Air permeability (cc/cm ² /sec.)	ASTM D 737:2004
Water vapour permeability (g/m ² /24h)	ASTM E 96
Tensile strength (N)	ASTM D 5034
Particle filtration (%)	IES RP-3-001-1985
Water absorption	AATCC 79:2007
Colour fastness to washing	AATCC 61:2007
Surface resistivity ((Ω/SQ)	ASTM D257
Sterilization Compatibility	Steam Autoclave, Gamma Radiation, Beta Radiation, ETO

GOosafe with SparMED!

Dainius Vasiliauskas
Regulatory Affairs Manager
SparMED ApS

Date: 01st of February 2017



Oosafe® IVF Laboratory Garments

GOO-CUST	Oosafe IVF Laboratory Garment Customized
GOO-M-01LB	Oosafe IVF Laboratory Garment Set - MAN - Light Blue, S
GOO-M-01NB	Oosafe IVF Laboratory Garment Set - MAN - Navy Blue, S
GOO-M-01NB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Navy Blue, S
GOO-M-01RB	Oosafe IVF Laboratory Garment Set - MAN - Royal Blue, S
GOO-M-01RB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Royal Blue, S
GOO-M-02LB	Oosafe IVF Laboratory Garment Set - MAN - Light Blue, M
GOO-M-02NB	Oosafe IVF Laboratory Garment Set - MAN - Navy Blue, M
GOO-M-02NB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Navy Blue, M
GOO-M-02RB	Oosafe IVF Laboratory Garment Set - MAN - Royal Blue, M
GOO-M-02RB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Royal Blue, M
GOO-M-03LB	Oosafe IVF Laboratory Garment Set - MAN - Light Blue, L
GOO-M-03NB	Oosafe IVF Laboratory Garment Set - MAN - Navy Blue, L
GOO-M-03NB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Navy Blue, L
GOO-M-03RB	Oosafe IVF Laboratory Garment Set - MAN - Royal Blue, L
GOO-M-03RB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Royal Blue, L
GOO-M-04LB	Oosafe IVF Laboratory Garment Set - MAN - Light Blue, XL
GOO-M-04NB	Oosafe IVF Laboratory Garment Set - MAN - Navy Blue, XL
GOO-M-04NB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Navy Blue, XL
GOO-M-04RB	Oosafe IVF Laboratory Garment Set - MAN - Royal Blue, XL
GOO-M-04RB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Royal Blue, XL
GOO-M-05LB	Oosafe IVF Laboratory Garment Set - MAN - Light Blue, XXL
GOO-M-05NB	Oosafe IVF Laboratory Garment Set - MAN - Navy Blue, XXL
GOO-M-05NB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Navy Blue, XXL
GOO-M-05RB	Oosafe IVF Laboratory Garment Set - MAN - Royal Blue, XXL
GOO-M-05RB-COAT	Oosafe IVF Laboratory Garment Coat - MAN - Royal Blue, XXL
GOO-W-01LB	Oosafe IVF Laboratory Garment Set - WOMAN - Light Blue, S
GOO-W-01NB	Oosafe IVF Laboratory Garment Set - WOMAN - Navy Blue, S
GOO-W-01NB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Navy Blue, S
GOO-W-01RB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Royal Blue, S
GOO-W-02LB	Oosafe IVF Laboratory Garment Set - WOMAN - Light Blue, M

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 Regulatory Affairs Manager
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Oosafe® IVF Laboratory Garments (cont.)

GOO-W-02NB	Oosafe IVF Laboratory Garment Set - WOMAN - Navy Blue, M
GOO-W-02NB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Navy Blue, M
GOO-W-02RB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Royal Blue, M
GOO-W-03LB	Oosafe IVF Laboratory Garment Set - WOMAN - Light Blue, L
GOO-W-03NB	Oosafe IVF Laboratory Garment Set - WOMAN - Navy Blue, L
GOO-W-03NB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Navy Blue, L
GOO-W-03RB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Royal Blue, L
GOO-W-04LB	Oosafe IVF Laboratory Garment Set - WOMAN - Light Blue, XL
GOO-W-04NB	Oosafe IVF Laboratory Garment Set - WOMAN - Navy Blue, XL
GOO-W-04NB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Navy Blue, XL
GOO-W-04RB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Royal Blue, XL
GOO-W-05LB	Oosafe IVF Laboratory Garment Set - WOMAN - Light Blue, XXL
GOO-W-05NB	Oosafe IVF Laboratory Garment Set - WOMAN - Navy Blue, XXL
GOO-W-05NB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Navy Blue, XXL
GOO-W-05RB-COAT	Oosafe IVF Laboratory Garment Coat - WOMAN - Royal Blue, XXL

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