

CERTIFICATIONS/CERTIFICATES:

EN ISO 9001
EN ISO 13485
EN ISO 14001
MDSAP 13485:2016
FDA Establishment Registration Number: 3006846316

EU DECLARATION OF CONFORMITY

(It is optional for the manufacturer to assign a number to the declaration of conformity)

(Annex IX to Regulation (EU) 2016/425)

1. PPE:

Personal protective gown **SAFELABGown**

2. Manufacturer's name and address:

Delta Med SpA, Via Guido Rossa No 20, Viadana (Mantua), Postcode 46019 - Italy

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Delta Med SpA, Via Guido Rossa No 20, Viadana (Mantua), Postcode 46019 - Italy

4. Subject matter of the declaration:

CODE	DESCRIPTION	SIZE
40.D1320.00	Gown SAFELABGown with elastic at the wrists non sterile	S
40.D1321.00	Gown SAFELABGown with elastic at the wrists non sterile	M
40.D1322.00	Gown SAFELABGown with elastic at the wrists non sterile	L
40.D1323.00	Gown SAFELABGown with elastic at the wrists non sterile	XL
40.D1324.00	Gown SAFELABGown with elastic at the wrists non sterile	XXL
40.D1330.00	Gown SAFELABGown with cuff at the wrists non sterile	S
40.D1331.00	Gown SAFELABGown with cuff at the wrists non sterile	M
40.D1332.00	Gown SAFELABGown with cuff at the wrists non sterile	L
40.D1333.00	Gown SAFELABGown with cuff at the wrists non sterile	XL
40.D1334.00	Gown SAFELABGown with cuff at the wrists non sterile	XXL
40.D1335.00	Gown SAFELABGown with cuff at the wrists non sterile	XXXL
42.D1320.00	Gown SAFELABGown with elastic at the wrists sterile	S
42.D1321.00	Gown SAFELABGown with elastic at the wrists sterile	M
42.D1322.00	Gown SAFELABGown with elastic at the wrists sterile	L
42.D1323.00	Gown SAFELABGown with elastic at the wrists sterile	XL
42.D1324.00	Gown SAFELABGown with elastic at the wrists sterile	XXL
42.D1330.00	Gown SAFELABGown with cuff at the wrists sterile	S
42.D1331.00	Gown SAFELABGown with cuff at the wrists sterile	M
42.D1332.00	Gown SAFELABGown with cuff at the wrists sterile	L
42.D1333.00	Gown SAFELABGown with cuff at the wrists sterile	XL
42.D1334.00	Gown SAFELABGown with cuff at the wrists sterile	XXL
42.D1335.00	Gown SAFELABGown with cuff at the wrists sterile	XXXL

5. The subject of the declaration of conformity referred to in point 4 complies with Regulation (EU) 2016/425

6. References to the relevant harmonised standards used:

EN ISO 13688:2013 - Protective clothing - General requirements
EN 13034:2005+A1: 2009 - Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
EN 14126:2003 - Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 14605:2005+A1:2009 - Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

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Sede produzione: Via E. G. Segrè, 6 - 42041 Sorbolo a Levante di Brescello (RE) - ITALY - Tel. +39 0522 480043

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7. Notified Body that carried out the EU-type examination (module B):

Centro Tessile Cotoniero e Abbigliamento SpA – Piazza Sant’Anna, 2 – 21052 Busto Arsizio (VA), Italy. Notified Body No 0624

which issued the EU-type examination certificate no CE0775210410-01-01

Module C 2

Conformity to type based on internal production control plus officially controlled product tests carried out at random intervals under the supervision of the notified body:

Centro Tessile Cotoniero e Abbigliamento SpA – Piazza Sant’Anna, 2 – 21052 Busto Arsizio (VA), Italy. Notified Body No 0624

Signed for and on behalf of: *Delta Med S.p.A.*

Place and date of issue: Viadana (MN), 19/05/2023

Dr Gabriele Giovanelli

[signature]:


