

**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 SURGICAL SAFE GOWN
  
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.D1770.00	Gown SURGICAL SAFE GOWN non sterile	S
40.D1771.00	Gown SURGICAL SAFE GOWN non sterile	M
40.D1772.00	Gown SURGICAL SAFE GOWN non sterile	L
40.D1773.00	Gown SURGICAL SAFE GOWN non sterile	XL
40.D1774.00	Gown SURGICAL SAFE GOWN non sterile	XXL
40.D1775.00	Gown SURGICAL SAFE GOWN non sterile	XXXL
42.D1770.00	Gown SURGICAL SAFE GOWN sterile	S
42.D1771.00	Gown SURGICAL SAFE GOWN sterile	M
42.D1772.00	Gown SURGICAL SAFE GOWN sterile	L
42.D1773.00	Gown SURGICAL SAFE GOWN sterile	XL
42.D1774.00	Gown SURGICAL SAFE GOWN sterile	XXL
30.D1770.00	Gown SURGICAL SAFE GOWN non sterile	S
30.D1771.00	Gown SURGICAL SAFE GOWN non sterile	M
30.D1772.00	Gown SURGICAL SAFE GOWN non sterile	L
30.D1773.00	Gown SURGICAL SAFE GOWN non sterile	XL
30.D1774.00	Gown SURGICAL SAFE GOWN non sterile	XXL
30.D1775.00	Gown SURGICAL SAFE GOWN non sterile	XXXL

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

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**6. References to the relevant harmonised standards used:**

EN ISO 13688:2022 - 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])

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

Centro Tessile Cottoniero 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 Cottoniero 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]:

