

**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:**

Protective Gown size S - Code 40.D2030.00, Protective Gown size M - Code 40.D2031.00  
Protective Gown size L - Code 40.D2032.00, Protective Gown size XL - Code 40.D2033.00  
Protective Gown size XXL - Code 40.D2034.00

**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:**

Protective Gown size S - Code 40.D2030.00, Protective Gown size M - Code 40.D2031.00  
Protective Gown size L - Code 40.D2032.00, Protective Gown size XL - Code 40.D2033.00  
Protective Gown size XXL - Code 40.D2034.00

**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])

**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 CE 0775200737-00-01

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), 06/10/2021

Dr Gabriele Giovanelli

[signature]:

