DELTA MED MEDICAL DEVICES
Solutions for Health

PART OF NUMANTEC HUMAN INNOVATION TECHNOLOGY

Via Guido Rossa, 20
46019 Viadana (MN) – Italy

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Fax +39 0375 785201
C. F. e P.IVA 01693020206

EU DECLARATION OF CONFORMITY
(Annex IX to Regulation (EU) 2016/425)

1. **PPE:** personal protective equipment Surgical Safe Gown
2. **Manufacturer's name and address:**
   Delta Med S.p.A., Via Guido Rossa N° 20, Viadana (MN), Postcode 46019 - Italy
3. **This declaration of conformity is issued under the sole responsibility of the manufacturer:**
   Delta Med S.p.A., Via Guido Rossa N° 20, Viadana (MN), 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
42.D1775.00	Gown SURGICAL SAFE GOWN sterile	XXXL
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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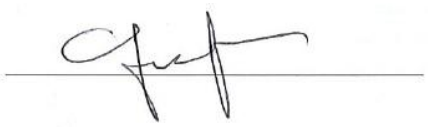
6. **References to the relevant harmonised standards used:**
   EN ISO 13688:2022 - Protective clothing - General requirements
   EN 13034:2009 - Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
   EN 14126:2004 - Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
   EN 14605:2009 - 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 Cotoniero e Abbigliamento S.p.A. –. Piazza Sant'Anna, 2 – 21052, Busto Arsizio (VA) Italy.
   Notified Body N° 0624
   which issued the EU-type examination certificate n. CE0775210410-01-02 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 S.p.A. –. Piazza Sant'Anna, 2 – 21052, Busto Arsizio (VA) Italy.
   Notified Body N° 0624

Signed for and on behalf of: Delta Med S.p.A.
Place and date of issue: Viadana (MN), 23/02/2026, Rev. 5

Dr Gabriele Giovanelli