

EU DECLARATION OF CONFORMITY



PPE Regulation (EU) 2016/425

1. PPE: This EU declaration of conformity refers to the following product:

Nitrile powder free gloves, 400 mm; article number 330811-330818

2. The Manufacturer name, address and authorized representative are as follows:

Protect2Clean GmbH

Erzberg 5

D-38126 Braunschweig

3. This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Protect2Clean GmbH

Erzberg 5

D-38126 Braunschweig

4. Detailed description of the PPE to allow traceability/identification of the PPE:

- **SimTec® - Steril**
- Size: 6,0 – 10,0
- Color: white
- length of 400mm
- Lot number & expiry date marked on the label
- SIMTEC NG040-S

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation Regulation (EU) 2016/425.

6. References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

- EN ISO 374-1:2016+A1:2018 / Type B (KPT)
- EN ISO 374-4:2013 (KPT)
- EN ISO 374-5:2016 (Protection against bacteria and fungi; Protection against viruses)
- EN 420:2003+A1:2009

7. SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Republic of Ireland Notified Body 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 2777/11793-03/E03-01.

8. This product is Category III and is subject to the conformity assessment procedure conformity to type based on an internal production control plus supervised product checks at random intervals (Module C2) and is under the surveillance of the notified body 2777.

Signed for and on behalf of:

Protect2Clean GmbH

Name and function of the undersigned:

Karoline Matzi,

Managing Director

Place and Date:

Braunschweig, 10.12.2024

Signature:

A handwritten signature in blue ink, appearing to read "K. Matzi", written over the "Signature:" label.