

# EU DECLARATION OF CONFORMITY

## Manufacturer Information

|                    |                                                                                        |
|--------------------|----------------------------------------------------------------------------------------|
| Manufacturer       | Quotex Systems Limited                                                                 |
| Address            | Radcliffe House, 3rd Floor East,<br>Blenheim Court, Lode Lane,<br>Solihull, UK B91 2AA |
| Responsible Person | Waheed Baig, Managing Director                                                         |
| Date of Issue      | 08/10/2025                                                                             |

## Notified Body Information

|                                  |                                                                                                    |
|----------------------------------|----------------------------------------------------------------------------------------------------|
| Notified Body                    | SATRA Technology Europe Ltd                                                                        |
| Address                          | Bracetown Business Park,<br>Clonee, Dublin 15<br>D15 YN2P, Ireland                                 |
| Notified Body No                 | 2777                                                                                               |
| Type Examination Certificate No. | 2777/21021-03/E01-01                                                                               |
| Assessment Module(s)             | Module B (EU Type Examination) and<br>Module C2 (Supervised Product<br>Checks at Random Intervals) |

## Object of the Declaration

|                     |                                                                                        |
|---------------------|----------------------------------------------------------------------------------------|
| Product Description | Disposable Nitrile Examination Gloves                                                  |
| Colour              | <div><div></div> Blue</div> <div><div></div> Black</div> <div><div></div> Purple</div> |
| Intended Use        | Single-use protective examination<br>gloves for medical and general use                |

## Conformity with EU Legislation

The object described in Section 2 conforms to the following Union harmonisation legislation:  
**Regulation (EU) 2016/425** on Personal Protective Equipment.  
Rule 1. Annex IX. Directive 93/42. Part II of the UK MDR 2002

## Standards and Technical Specifications

| Standard / Specification |                             |
|--------------------------|-----------------------------|
| EN ISO 21420:2020        | EN ISO 374-1:2016 + A1:2018 |
| EN ISO 374-5:2016        | BS EN ISO 20417:2021        |
| BS EN ISO 14971:2019     | BS EN ISO 15223-1:2021      |
| BS EN ISO 10993-5:2009   | BS EN ISO 10993-1: 2020     |
| BS EN ISO 10993-10: 2023 | BS EN ISO 10993-23: 2021    |
| BS EN 455-1:2020+A1:2022 | BS EN 455-2:2024            |
| BS EN 455-3:2023         | BS EN 455-4:2009            |

| Product Codes and Sizes |         |              |                 |             |                  |
|-------------------------|---------|--------------|-----------------|-------------|------------------|
| Product Code            | Size    | Nominal Size | Palm Width (mm) | Length (mm) | Thickness (mm)   |
| QTX2404 / 613536        | Small   | 6 (S)        | <80             | 240±10      | 0.08 (fingertip) |
| QTX2405 / 613537        | Medium  | 7 (M)        | 8±5             | 250±10      | 0.08 (fingertip) |
| QTX2406 / 613538        | Large   | 8 (L)        | 100±5           | 250±10      | 0.08 (fingertip) |
| QTX2407 / 613539        | X-Large | 9 (XL)       | >110            | 250±10      | 0.08 (fingertip) |

|                     |                                                                                       |
|---------------------|---------------------------------------------------------------------------------------|
| Signed on behalf of | Quotex Systems Limited                                                                |
| Name                | Waheed Baig                                                                           |
| Position            | Managing Director                                                                     |
| Date of Issue       | 08/10/2025                                                                            |
| Signature           |  |



**UK OFFICE**  
Quotex Systems Ltd  
Radcliffe House, 3rd Floor East,  
Blenheim Court, Lode Lane,  
Solihull. B91 2AA.

**CHINA OFFICE**  
2002 No.8 Da Cheng Lane  
Liangxi  
Wuxi  
Jiangsu  
China 214000

**Tel:** +44 (0) 1564 757 320  
**Email:** sales@quotexltd.com

**www.quotexltd.com**