

EU DECLARATION OF CONFORMITY

Manufacturer Information

Manufacturer	Quotex Systems Limited
Address	Radcliffe House, 3rd Floor East, Blenheim Court, Lode Lane, Solihull, UK B91 2AA
Responsible Person	Waheed Baig, Managing Director
Date of Issue	8/10/2025

Notified Body Information

Notified Body	SATRA Technology Europe Ltd
Address	Bracetown Business Park, Clonee, Dublin 15 D15 YN2P, Ireland
Notified Body No	2777
Type Examination Certificate No.	2777/14873-03/E01-01
Assessment Module(s)	Module B (EU Type Examination) and Module C2 (Supervised Product Checks at Random Intervals)

Object of the Declaration

Product Description	Disposable Vinyl Examination Gloves
Colour	☒ Blue ☐ Black ☐ Clear
Intended Use	Single-use protective examination 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 374-5:2016 BS EN ISO 14971:2019 BS EN ISO 10993-5:2009 BS EN ISO 10993-10: 2023 BS EN 455-1:2020+A1:2022 BS EN 455-3:2023	EN ISO 374-1:2016 + A1:2018 BS EN ISO 20417:2021 BS EN ISO 15223-1:2021 BS EN ISO 10993-1: 2020 BS EN ISO 10993-23: 2021 BS EN 455-2:2024 BS EN 455-4:2009

Product Codes and Sizes					
Product Code	Size	Nominal Size	Palm Width (mm)	Length (mm)	Thickness (mm)
QTX2104/614002 QTX2125/613996	Small	7 (S)	85+/-5	230±10	0.08 (fingertip)
QTX2105/614000 QTX2126/610017	Medium	8 (M)	95+/-5	230±10	0.08 (fingertip)
QTX2106/613998 QTX2127/610018	Large	9 (L)	105+/-5	230±10	0.08 (fingertip)
QTX2107/614003 QTX2299/613997	X-Large	10 (XL)	115+/-5	230±10	0.08 (fingertip)

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



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