

EU DECLARATION OF CONFORMITY

Annex IX Personal Protective Equipment Regulation (EU) 2016/425

1. This EU Declaration of conformity refers to the following products

Product Name	Product Code / Model	Classification/Type	Batch No.
Patient Examination Gloves	MEDCARE Nitrile ExG / NITRA PROTECT	PPE CAT III, Type B	N/A

2. The Manufacturer's name and address is as follows:

Name:	Newsonic Solutions Ltd.
Address:	Unit 2012 Commercial Wealth Centre, 52-56 Kwong Wa Street, Hong Kong, SAR, China

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

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

MEDCARE Nitrile ExG: Disposable Patient Examination Gloves, Colour Blue, Available in Size S, M, L, XL



The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

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:

No.	Harmonized Standards Applied.
1,2,3	EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

The notified body SATRA Technology Europe Ltd, (Notified Body Number: 2777), with address in Bracetown Business Park, Clonee, Dublin 15D15 YN2P Ireland and Tel: +353 (0) 1 437 2484, performed the EU examination (Module B) and issued the EU type- examination certificate.

No.	EU Type Examination (Module B) Certificate Number
1	2777/16193-01/E00-00

Product

Category:

This Product is Category III and is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (module C2) or conformity to type based on quality assurance of the production process (module D) under surveillance of the notified body SATRA (NB 2777).

Date of Issue:
10th March 2021



For and on behalf of
Newsonic Solutions Limited

Authorized Signature(s)

Alfonso Di Pasquale
Legal Representative