



**EU Declaration of Conformity No. 2777/11050-02/E04-01**

1. PPE subject of this declaration: **Disposable nitrile gloves**

2. Issued by:

**Mooni Limited  
Room 1401 Cambridge House  
26 – 28 Cameron Road  
Tsimshatsui  
Kowloon  
Hong Kong**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: **Mooni Limited** (as above).

4. Object of the declaration:

**NG-5 Blue XS  
NG-5 Blue S  
NG-5 Blue M  
NG-5 Blue L  
NG-5 Blue XL**

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

**Personal Protective Equipment Regulation 2016/425**

6. Conformity is declared in relation to the following harmonised standards used in the assessment of the PPE product described in 4, above:

**EN ISO 374-1:2016 EN 374-4:2013 EN ISO 374-5:2016 EN 420:2003+A1:2009**

7. EU type examination certification (Module B) issued by:

**SATRA Technology Europe Limited, Notified Body No. 2777  
EU type examination certificate number 2777/11050-02/E04-01**

8. The PPE is subject to the conformity assessment procedure:

**Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under the surveillance of the SATRA Technology Europe Limited, Notified Body No. 2777.**

9. Meet the provision of Council Directive 93/42/EEC as amended by 2007/47/EEC and Provisions of the Regulation (EU) 2017/745 which apply to them. Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex VIII.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015 EN ISO 14971:2012, EN ISO 13485:2016.



Conformity assessment procedure: Annex VIII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC and Article 52 MDR 2017/745.

The CE declaration of conformity is issued under the sole responsibility of Mooni Ltd.



Signed for and on behalf of Mooni Limited  
Done at Kowloon, Hong Kong, on 19 March 2021

DocuSigned by:  
  
8580E6937D2E4ED...

Staffan Bern  
CEO & Founder



**EU Declaration of Conformity No. 2777/11050-02/E04-01**

3. PPE subject of this declaration: **Disposable nitrile gloves**

4. Issued by:

**Mooni International AB  
Brädgårdsvägen 28 1TR  
236 32 Höllviken  
Sweden**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer's authorised representative: **Mooni International AB** (as above).

5. Object of the declaration:

**NG-5 Blue XS  
NG-5 Blue S  
NG-5 Blue M  
NG-5 Blue L  
NG-5 Blue XL**

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

**Personal Protective Equipment Regulation 2016/425**

10. Conformity is declared in relation to the following harmonised standards used in the assessment of the PPE product described in 4, above:

**EN ISO 374-1:2016 EN 374-4:2013 EN ISO 374-5:2016 EN 420:2003+A1:2009**

11. EU type examination certification (Module B) issued by:

**SATRA Technology Europe Limited, Notified Body No. 2777  
EU type examination certificate number 2777/11050-02/E04-01**

12. The PPE is subject to the conformity assessment procedure:

**Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under the surveillance of the SATRA Technology Europe Limited, Notified Body No. 2777.**

13.

Signed for and on behalf of Mooni International AB  
Done at Höllviken, Sweden, on 19 March 2021

DocuSigned by:  
  
8580E6937D2E4ED...

**Staffan Bern  
CEO**