



EU Declaration of Conformity No. 2777/11521-02/E21-01

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
NG-5 Blue Purple
NG-5 Cobalt Blue
NG-5 White
NG-5 Black**

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{2}11521-02{2}E21-01 NG-5 (ID 447540)

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
Stockholm, on 31st January 2022

A handwritten signature in black ink, appearing to read "Staffan Bern".

Staffan Bern
CEO & Founder

EU Declaration of Conformity No. 2777/11521-02/E21-01

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

4. Issued by:

**Supply Value Sweden AB
Mailbox 3102
112 73 STOCKHOLM
Sweden**

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

5. Object of the declaration:

**NG-5 Blue
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NG-5 Cobalt Blue
NG-5 White
NG-5 Black**

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 2777/11521-02/E21-01

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 Supply Value Sweden AB. Stockholm, Sweden, on 31st January 2022


Staffan Bern
CEO