Manufacturer: Mooni Ltd.
1401 Cambridge House
26-28 Cameron Road
Tsimshatsui
Kowloon, Hong Kong
www.moonigroup.com
info@mooni.com
+46708108676

DECLARATION OF COMPLIANCE

Declaration of Compliance with:

- This product complies with Regulation (EC) No. 10/2011
- This product complies with Regulation (EC) No. 1935/2004
- This product complies with Regulation (EC) No. 2023/2006

This plastic gloves has been manufactured only with monomers, other starting substances and additives that are authorized under Regulation (EC) No.10/2011 was performed from this product.

Product: Mooni MULTI-PURPOSE NITRILE DISPOSABLE GLOVES NON-STERILE, POWDER FREE, AMBIDEXTROUS

Model: NG-5 Blue

Glove Size: XS, S, M, L, XL

Specific Migration Limits (SMLs):

All ingredients, starting monomers, additives used in manufacturing this glove comply with:

- Any positive list
- Any relevant SML (Specific Migration Limit) or restrictions as specified in the applicable EU-28 food legislations

Migration tests:

Total overall migration test is conducted according to 10/2011/EU.
Test conditions: 120 minutes at 70°C.
Test Simulants: Acetic acid 3%, ethanol 10% Deionized water, Rectified olive oil. The products comply with migration limits

Simulant Used	Time	Temperature	Max. Permissible Limit	Overall Migration
3% Acetic acid aqueous solution	2.0 hr(s)	70°C	10mg/dm^2	7.2mg/dm^2
10% Ethanol aqueous solution	2.0 hr(s)	70°C	10mg/dm^2	4.6mg/dm^2
Rectified olive oil	2.0 hr(s)	70°C	10mg/dm^2	<3.0mg/dm^2

Information about the compliance of substances subject to purity criteria:

- There are no substances to purity criteria.
- There are no substances subjected to restrictions apart from the Specific Migration Limits (SMLs)

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Information about the use of "dual-use" additives in the material:	No dual use additives were used in the manufacture of this product.
Conditions of use:	Type(s) of food with which is intended to be in contact - All foods. The ratio of food contact surface are to volume used to establish the compliance of the material of article - The complinance testing was done under the conditions set out in Regulations (EC) No. 10/2011 using a surface to volume (s/v) contact ratio of 6 dm^2/kg
Functional barrier:	There is no functional barrier present.
Additional info:	Can be provided up on request at info@mooni.com

Date: 2021-07-05

Made By:

DocuSigned by:
Patrik Bern
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Patrik Bern
Vice President

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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.

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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.

CE

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

DocuSigned by:
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Staffan Bern
CEO & Founder

mooni

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 Hőllviken
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:

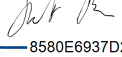
SATRA Technology Europe Limited, Notified Body No. 2777
EU type examination certificate number 2777/11050-02/E04-01

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 Hőllviken, Sweden, on 19 March 2021

DocuSigned by:

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Staffan Bern
CEO

EU DECLARATION OF CONFORMITY

We, the undersigned, hereby declare that the disposable device(s) specified below under our sole responsibility meet the provisions of Regulation (EU) 2017/745 on Medical Devices and are in conformance with Regulation (EU) 2016/425 on Personal Protective Equipment

Manufacturer:
Mooni Ltd.
Room 1401 Cambridge House
26 – 28 Cameron Road
Tsimshatsui
Kowloon
Hong Kong

EU Authorized Representative:
Mooni International AB
Brädgårdsvägen 28
236 31 Höllviken
Sweden
Phone: +46708108676
Email: patrik.bern@mooni.com

Product: Mooni MULTI-PURPOSE NITRILE DISPOSABLE GLOVES NON-STERILE, POWDER FREE, AMBIDEXTROUS

Model: NG-5 Blue
Description: Single use, non-sterile, powder-free nitrile examination gloves.

Glove Size: S, M, L, XL

Basic UDI-DI: 73400948
Size S: 7340094808506
Size M: 7340094808513
Size L: 7340094808520
Size XL: 7340094808537

Classification: Medical Device Regulation (EU) 2017/745 – Class 1
Personal Protective Equipment Regulation (EU) 2016/425 – Category III-Complex
Intended Use: The gloves shall protect the wearer against chemical splash and micro-organism hazards. Gloves are also intended for the use in the medical field to protect patient and user from cross-contamination.

EU type examination certification (Module B, Personal Protective Equipment Regulation) issued by:

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

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.

The object of the declaration described is in conformity with the

Relevant EU harmonization legislation:	And European Standards:
Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2016/425 on Personal Protective Equipment	EN ISO 374-1:2016 EN 374-4:2013 EN ISO 374-5:2016 EN 420:2003+A1:2009 EN455-1:2000 EN455-2:2015 EN455-3:2015 ISO 14971:2012 EN ISO 13485:2016

Signed for and on behalf of Mooni Limited
Done at Kowloon, Hong Kong, on 11 June 2021

DocuSigned by:
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Staffan Bern
CEO & Founder