



## 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.  
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26 – 28 Cameron Road  
Tsimshatsui  
Kowloon  
Hong Kong

**EU Authorized Representative:**

Mooni International AB  
Brädgårdsvägen 28  
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Phone: +46708108676  
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**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