



PROFESSIONAL LATEX SDN. BHD.

(1038089-A)

博利手套有限公司

LOT 52, JALAN LOGAM 2, KAMUNTING RAYA INDUSTRIAL,
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Tel : +605 891 1637 Fax : +605 891 1417
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DECLARATION OF CONFORMITY

We, **Professional Latex Sdn. Bhd. (1038089-A)**
Lot 52, Jalan Logam 2, Kamunting Raya Industrial,
34600 Kamunting, Perak, Malaysia.
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Declare under our sole responsibility that the medical device described hereafter:

NON-STERILE POWDER FREE NITRILE EXAMINATION GLOVES

Under Classification (MDD, Annex IX): **Class I, Rule 5**

Has meet the provisions of the MDD 93/42/EEC (as amended by Directive 2007/47/EC)

And

Under classification (First Schedule, Appendix 1): **Class A, Rule 5**

Has meet the provisions of the Medical Device regulation 2012 under the Medical Device Act 2012 and other relevant harmonized standards as follows:-

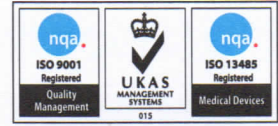
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| EN ISO 13485 | Medical Devices – Quality Management Systems – Requirements for regulatory purposes |
| ISO 14971 | Medical Devices – Application of risk management to medical devices |
| ISO 10993-10 | Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity |
| ISO 15223-1 | Medical Devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements |
| EN 455-1 | Requirements and Testing for Freedom from Holes |
| EN 455-2 | Requirements and Testing for Physical Properties |
| EN 455-3 | Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation |
| EN 455-4 | Medical Gloves for Single Use – Part 4: Requirements and testing for shelf life determination |
| EN 374-1 | Protective glove against chemicals and micro-organism – Part 1: Terminology and Performance requirement |
| EN 374-2 | Protective glove against chemicals and micro-organisms – Part 2: Determination of resistance to penetration |
| ASTM D6319 | Standard Specification for Nitrile Examination Gloves for Medical Application |



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|------------|---|
| ASTM D5151 | Standard Test Method for Detection of Holes in Medical Gloves |
| ASTM D5712 | Standard Test Method for Analysis of Protein in Natural Rubber and its Products using the Modified Lowry Method |
| ASTM D412 | Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers - Tension |

Commission Regulation (EC) No. 1935/2004 : Material and articles intended to come into contact with food

In House Standards : Product free from Plasticizers, contain No Phthalates esters, Silicone oil and Amide

Following the provisions in conformity assessment procedure listed in Annex VII of Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC) and as stated in schedule three in Medical Device Regulation 2012. This declaration is supported by the Quality System certification based on the harmonized standard **ISO 13485: 2016**, Quality System Certificate with reference number **66352** issued for the first time on **9th May 2017** and delivered by Notified Body **NQA Certification Ltd. located at Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, United Kingdom.**

The European Authorized Representative, **mdi Europa GmbH** is located at **Langenhagener Str. 71, 30855 Langenhagen, Germany.**

All supporting documentations are retained at the premises of the manufacturer.

Professional Latex Sdn. Bhd.

Authorized Signatory



Name: Kok Yoon Lim
Title: Managing Director
Date: 28th April 2020