Hartalega

Innovation & Quality

# EU DECLARATION OF CONFORMITY

| | | |
|---|---|---|
| Manufacturer | : | Hartalega NGC Sdn. Bhd. |
| Manufacturer's Address | : | No.1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia. |
| EU Representative | : | MDSS GmbH<br>Schiffgraben 41, 30175 Hannover, Germany. |
| Product Description (EU MDR) | : | Nitrile Powder Free Examination Gloves |
| Device Classification (EU MDR) | : | Class I, according to Annex VIII of Regulation (EU) 2017/745 |
| Rule(s) | : | 1 and 5 |
| Conformity Assessment Procedure | : | Annex II and Annex III |
| Basic UDI-DI | : | 955100777HNGCTFMD005AQ8 |
| Authorized Representative SRN | : | DE-AR-000005430 |
| Manufacturer SRN | : | MY-MF-000010459 |
| Product Description (EU PPER) | : | Nitrile Powder Free Examination Gloves (≥ 2.2 mil)<br>Available in standard minimum 240mm length or a longer cuff variant of 280mm |
| Device Classification (EU PPER) | : | Category III (Type B) |
| EU Type-Examination Certificate Number (EU PPER) | : | 2777/11578-04/E00-00 |
| Intended Purpose | : | Nitrile Powder Free Examination Gloves are intended to be used to contribute to prevent cross contaminations in the framework of medical examinations and diagnostic/ therapeutic procedures conducted under non-sterile conditions.<br>and<br>Nitrile Powder Free Examination Gloves is intended to protect users from substances and mixtures which are hazardous to health and harmful biological agents that may cause very serious consequences or irreversible damage to health. |
| Standard Reference | : | Attachment I |
| Reference to Trade Name | : | Attachment II |



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We, Hartalega NGC Sdn. Bhd. herewith declared that above mentioned device:

- is in conformity with the Regulation (EU) 2017/745 of The European Parliament and of The Council of medical devices.
- is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment.
- is subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee D15YN2P, Republic of Ireland (Notified Body number 2777).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Hartalega NGC Sdn. Bhd.

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 13th August 2026

Signed on Behalf of Hartalega NGC Sdn. Bhd. :

Name : NURUL AISYAH KONG
Position : GENERAL MANAGER - QUALITY ASSURANCE



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## ATTACHMENT I

## STANDARD REFERENCE (MDR)

| Standard | Title |
|---|---|
| ISO 9001:2015/Amd 1:2024 | Quality Management Systems – Requirements<br>Amendment 1: Climate action changes |
| EN ISO 13485:2016+A11:2021 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN 455-1:2020+A2:2024 | Medical Gloves for Single Use<br>Part 1: Requirements and Testing for Freedom from Holes |
| BS EN 455-1:2020+A2:2024 | Medical Gloves for Single Use<br>Part 1: Requirements and Testing for Freedom from Holes |
| EN 455-2:2024 | Medical Gloves for Single Use<br>Part 2: Requirements and Testing for Physical Properties |
| BS EN 455-2:2024 | Medical Gloves for Single Use<br>Part 2: Requirements and Testing for Physical Properties |
| EN 455-3:2023 | Medical Gloves for Single Use<br>Part 3: Requirements and Testing for Biological Evaluation |
| BS EN 455-3:2023 | Medical Gloves for Single Use<br>Part 3: Requirements and Testing for Biological Evaluation |
| EN 455-4:2009 | Medical Gloves for Single Use<br>Part 4: Requirements and Testing for Shelf-Life Determination |
| BS EN 455-4:2009 | Medical Gloves for Single Use<br>Part 4: Requirements and Testing for Shelf-Life Determination |
| EN 455-5:2025 | Medical gloves for single use<br>Part 5: Extractable chemical residues |
| BS EN 455-5:2025 | Medical gloves for single use<br>Part 5: Extractable chemical residues |
| BS EN ISO 20417:2021 | Medical devices – Information to be Supplied by the Manufacturer |
| BS EN ISO 14971:2019+A11:2021 | Medical Devices – Application of Risk Management to Medical Devices |
| IEC 62366-1: 2015/Amd 1:2020 | Medical devices — Part 1: Application of usability engineering to medical devices |
| EN 62366 – 1: 2015+A1:2020 | Medical devices — Part 1: Application of usability engineering to medical devices |
| IEC/TR 62366 – 2:2016 | Medical devices — Part 2: Guidance on the application of usability engineering to medical devices |
| ISO 15223-1:2021/Amd1:2025 | Medical Devices –Symbol to be Used with Information to be Supplied by the Manufacturer |



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| Standard | Title |
|---|---|
| | Part 1: General Requirements<br>Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific |
| BS EN ISO 15223-1:2021+A1:2025 | Medical devices – Symbols to be used with information to be supplied by the manufacturer<br>Part 1: General Requirements |
| ISO 10993-1:2025 | Biological Evaluation of Medical Devices<br>Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process |
| BS EN ISO 10993 – 1: 2025 | Biological Evaluation of Medical Devices<br>Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process |
| ISO 10993-5:2009 | Biological Evaluation of Medical Devices<br>Part 5: Tests for In Vitro Cytotoxicity |
| BS EN ISO 10993 – 5:2009+A11:2025 | Biological Evaluation of Medical Devices<br>Part 5: Tests for In Vitro Cytotoxicity |
| ISO 10993-10:2021 | Biological Evaluation of Medical Devices<br>Part 10: Tests for Skin Sensitization |
| BS EN ISO 10993 – 10:2023 | Biological Evaluation of Medical Devices<br>Part 10: Tests for Skin Sensitization |
| ISO 10993-11:2017 | Biological Evaluation of Medical Devices<br>Part 11: Tests for Systemic Toxicity |
| BS EN ISO 10993 – 11:2018 | Biological Evaluation of Medical Devices<br>Part 11: Tests for Systemic Toxicity |
| ISO 10993-18:2020/ Amd 1:2022 | Biological Evaluation of Medical Devices<br>Part 18: Chemical Characterization of Medical Device Materials Within A Risk Management Process<br>Amendment 1: Determination of the uncertainty factor |
| BS EN ISO 10993 – 18:2020+A1:2023 | Biological Evaluation of Medical Devices<br>Part 18: Chemical Characterization of Medical Device Materials Within A Risk Management Process |
| ISO 10993-23:2021/ Amd1: 2025 | Biological Evaluation of Medical Devices<br>Part 23: Tests for Irritation<br>Amendment 1: Additional in vitro reconstructed human epidermis model |
| BS EN ISO 10993 – 23:2021+A1: 2025 | Biological Evaluation of Medical Devices<br>Part 23: Tests for Irritation |
| ISO 2859-1:2026 | Sampling Procedures for Inspection by Attributes<br>Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-By-Lot Inspection |



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| Standard | Title |
|---|---|
| ASTM D4169-23e1 | Standard Practice for Performance Testing of Shipping Containers and Systems |

**STANDARD REFERENCE (PPER)**

| Standard | Title |
|---|---|
| EN ISO 21420:2020 | Protective gloves - General requirements and test methods |
| EN ISO 374-1:2016+A1:2018 | Protective gloves against dangerous chemicals and micro-organisms -<br>Part 1: Terminology and performance requirements for chemical risks |
| EN ISO 374-5:2016 | Protective gloves against dangerous chemicals and micro-organisms -<br>Part 5: Terminology and performance requirements for micro-organisms risks |
| EN 421:2010 | Protective gloves against ionizing radiation and radioactive contamination |



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## ATTACHMENT II

| Product or Trade Name | Reference Number |
|---|---|
| SANA SWISS BLUE NITRILE PF EXAM GLOVE | XS: 470099-1N<br>S: 470100-1N<br>M: 470101-1N<br>L: 470102-1N<br>XL: 470103-1N |
| SANA SWISS BLACK NITRILE PF EXAM GLOVES | XS: 470007-1N<br>S: 470008-1N<br>M: 470009-1N<br>L: 470010-1N<br>XL: 470011-1N |
| SANA SWISS WHITE NITRILE PF EXAM GLOVES | XS: 470104-1N<br>S: 470104-2N<br>M: 470105-1N<br>L: 470106-1N<br>XL: 470107-1N |



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