



# CERTIFICATE



SIRIM QAS International Sdn. Bhd. hereby certifies that

**SSN MEDICAL PRODUCTS SDN. BHD.**  
**LOT 31793**  
**JALAN KPB 12, KAMPUNG BARU BALAKONG**  
**43300 SERI KEMBANGAN**  
**SELANGOR DARUL EHSAN**  
**MALAYSIA**

has implemented a Quality Management System for Medical Devices complying with



## ISO 13485 : 2016

*Medical Devices - Quality Management System – Requirements For Regulatory Purposes (In Compliance with Act 737 and Medical Device Regulations 2012 requirements)*

### Scope of Certification

- 1) **MANUFACTURE & SUPPLY; AND DISTRIBUTION OF**
  - i. **NON-STERILE NATURAL RUBBER LATEX EXAMINATION GLOVE;**
  - ii. **NON-STERILE SYNTHETIC RUBBER LATEX EXAMINATION GLOVE;**
  - iii. **NON-STERILE NATURAL RUBBER LATEX SURGICAL GLOVE;**
  - iv. **NON-STERILE SYNTHETIC RUBBER LATEX SURGICAL GLOVE;**
  - v. **STERILE NATURAL RUBBER LATEX SURGICAL GLOVE.**
- 2) **DESIGN, DEVELOPMENT AND MANUFACTURE OF NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX CONTRACEPTIVE MALE CONDOMS.**

#### **RISK CLASSIFICATION OF MEDICAL DEVICE:**

- i. **LATEX EXAMINATION GLOVES – (CLASS A, RULE 5)**
- ii. **NITRILE EXAMINATION GLOVES – (CLASS A, RULE 5)**
- iii. **LATEX SURGICAL GLOVES – (CLASS B, RULE 6)**
- iv. **NITRILE SURGICAL GLOVES – (CLASS B, RULE 6)**
- v. **CONDOM - (CLASS C, RULE 16)**

Issue Date : 25 February 2021  
Original certification date : 25 February 2021  
Expiry Date : 24 February 2024  
Certification No. : QMS-MD 00178



SIRIM QAS INTERNATIONAL SDN. BHD.  
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<http://www.sirim-qas.com.my>  
<http://www.malaysiancertified.com.my>

This certificate is granted subject to the terms and conditions as stated in the Certification Agreement.



THE INTERNATIONAL CERTIFICATION NETWORK

## CERTIFICATE

SIRIM QAS International Sdn. Bhd. has issued an IQNet recognized certificate that the organization:

**SSN MEDICAL PRODUCTS SDN. BHD.**

LOT 31793  
JALAN KPB 12, KAMPUNG BARU BALAKONG  
43300 SERI KEMBANGAN  
SELANGOR DARUL EHSAN  
MALAYSIA

has implemented and maintains a

**QUALITY MANAGEMENT SYSTEM**

for the following scope:

- 1) MANUFACTURE & SUPPLY; AND DISTRIBUTION OF
  - i. NON-STERILE NATURAL RUBBER LATEX EXAMINATION GLOVE;
  - ii. NON-STERILE SYNTHETIC RUBBER LATEX EXAMINATION GLOVE;
  - iii. NON-STERILE NATURAL RUBBER LATEX SURGICAL GLOVE;
  - iv. NON-STERILE SYNTHETIC RUBBER LATEX SURGICAL GLOVE;
  - v. STERILE NATURAL RUBBER LATEX SURGICAL GLOVE.
- 2) DESIGN, DEVELOPMENT AND MANUFACTURE OF NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX CONTRACEPTIVE MALE CONDOMS.

**RISK CLASSIFICATION OF MEDICAL DEVICE :**

- i. LATEX EXAMINATION GLOVES – (CLASS A, RULE 5)
- ii. NITRILE EXAMINATION GLOVES – (CLASS A, RULE 5)
- iii. LATEX SURGICAL GLOVES – (CLASS B, RULE 6)
- iv. NITRILE SURGICAL GLOVES – (CLASS B, RULE 6)
- v. CONDOM - (CLASS C, RULE 16)

which fulfils the requirements of the following standard:

### ISO 13485 : 2016

Issued on : 25 February 2021

First issued on : 25 February 2021

Expires on : 24 February 2024

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document



Registration Number : **MY – QMS-MD 00178**

  
Alex Stoichitoiu

President of IQNet

  
Nur Fadhliah binti Muhammad

Chief Executive Officer  
SIRIM QAS International Sdn Bhd



*IQNet Partners\*:*

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
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IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.