AAMEDIX
Glove Sdn. Bhd.

EU Declaration of Conformity
Latex Surgical Powdered Gloves

PRODUCT DESCRIPTION

1. Product Name: Latex Sterile Powdered Textured Surgical Gloves
2. Product Classification: Class IIa under Medical Device Regulation (EU) 2017/745 Annex VIII Rule 7

ADDRESS:

AAMedix Glove Sdn Bhd.
Unit 19D, Level 19, No. 16, Persiaran Setia Dagang,
Bandar Setia Alam, 40170 Shah Alam,
Selangor Darul Ehsan, Malaysia.
Tel: +603-3359 2650 ; Fax: +603-3359 2657
Email: support@aamedix-glove.com ; anson@aamedix-glove.com

Single Registration Number (SRN): MY-MF-000025086

AUTHORIZED REPRESENTATIVE:

EU REP **CMC Medical Devices & Drugs S.L.**
C/Horacio Lengo N°18,
Malaga, CP29006
Spain

Single Registration Number (SRN):
ES-AR-000000293

We, **AAMedix Glove Sdn. Bhd.** as the legal manufacturer declare under our sole responsibility that the medical devices listed below conform to the requirement of the Medical Device Regulation (EU) 2017/745.

Nitrile Sterile Surgical Gloves

- AAMEDIX LATEX STERILE POWDERED TEXTURED SURGICAL GLOVE

Basic UDI-DI : 95510152547179QV

UDI Numbers: Attachment A

INTENDED USE: used to be worn by operating room personnel during surgery to prevent the transmissions of the infections or cross-contamination between the patient and user

It is declared that above devices meet the requirement of the Medical Device Regulation (EU) 2017/745.

The undersigned, hereby declare that the disposable device(s) specified above are following the EU Type Examination and conformity with the provisions of the new PPE Regulation (EU) 2016/425- Cat III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016+ A1:2018, EN ISO 21420:2020, EN ISO 374-4:2019 and EN ISO 374-5:2016.

The fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated under the supervision of the following notified body:

Unit 19D, Level 19, No. 16, Persiaran Setia Dagang, Bandar Setia Alam, 40170 Shah Alam, Selangor Darul Ehsan, Malaysia
Tel : +603-3359 2650 Fax : +603-3359 2657 email : support@aamedix-glove.com Website : www.aamedix-glove.com

1. TÜV SÜD Product Service GmbH, Zertifiziertelle für Medizinprodukte / Certification Body for Medical Products Ridlerstr. 65 80339 Munich Germany. Notified body No. 0123.
2.

ATTACHMENT A Declaration of Conformity (*Latex Surgical Gloves*)

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
AAMEDIX LATEX STERILE POWDERED TEXTURED SURGICAL GLOVE	6.0	19551015255605
	6.5	19551015255650
	7.0	19551015255704
	7.5	19551015255759
	8.0	19551015255803
	8.5	19551015255858

In accordance with Annex VIII, Medical Device Regulation (EU) 2017/745, the device listed above are non-invasive transient devices and are Class IIa devices under Rule 7 & as Rules 1, 2, 3, 4 and 5 do not apply.

The following person is responsible for the signature of the document:

Name and Address: AAMedix Glove Sdn. Bhd. Unit 19D, Level 19, No. 16, Persiaran Setia Dagang, Bandar Setia Alam, 40170 Shah Alam,Selangor Darul Ehsan, Malaysia.

Authorized Signature: 

Date: May 19, 2026

Name of responsible Person: Ker Eng Soon

Position: Vice President

Unit 19D, Level 19, No. 16, Persiaran Setia Dagang, Bandar Setia Alam, 40170 Shah Alam, Selangor Darul Ehsan, Malaysia
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