

EU Declaration of Conformity
Latex Examination Gloves

PRODUCT DESCRIPTION

1. Product Name: Latex Examination Gloves
2. Product Classification: Class I under Medical Device Regulation (EU) 2017/745 Annex VIII Rule 1 & 5

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
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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 Examination Gloves

- AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE
- AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – BLACK
- AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – DOUBLE CHLORINATED
- AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – HIGH RISK

Basic UDI-DI : 95510152547172QF

UDI Numbers: Attachment A

INTENDED USE: A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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:

1. SATRA Technology Europe Ltd. Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland is identical to the PPE EU Certificate of Conformity No: 2777/10906-04/E02-01. Notified body No. 2777.
- 2.

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

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE	XS	9551015252454
	S	9551015252461
	M	9551015252478
	L	9551015252485
	XL	9551015252492
AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – BLACK COLOR	XS	9551015251556
	S	9551015251563
	M	9551015251570
	L	9551015251587
	XL	9551015251594
AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – DOUBLE CHLORINATED	XS	9551015251358
	S	9551015251365
	M	9551015251372
	L	9551015251389
	XL	9551015251396
AAMEDIX LATEX POWDER FREE EXAMINATION GLOVE – HIGH RISK	XS	9551015254458
	S	9551015254465
	M	9551015254472
	L	9551015254489
	XL	9551015254496

In accordance with Annex VIII, Medical Device Regulation (EU) 2017/745, the device listed above are non-invasive transient devices and are Class I devices under Rule 1 & 5 as Rules 2, 3, and 4 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: November 19, 2025

Name of responsible Person: Ker Eng Soon

Position: Vice President