AAMEDIX
Glove Sdn. Bhd.

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

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.

Latex Examination Gloves

- AAMEDIX LATEX POWDERED EXAMINATION GLOVE

Basic UDI-DI : 0723860471738X

UDI Numbers: Attachment A

INTENDED USE: A 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.

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

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: 2777/10905-03/E02-01. Notified body No. 2777.

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

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
AAMEDIX LATEX POWDERED EXAMINATION GLOVES	XS	00723860012258
	S	00723860012265
	M	00723860012272
	L	00723860012289
	XL	00723860012296

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

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