

EU Declaration of Conformity
Nitrile Examination Gloves

PRODUCT DESCRIPTION

1. Product Name: Nitrile 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.
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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 NITRILE POWDER FREE EXAMINATION GLOVES – BLUE COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – BLACK COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – RED COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – DARK BLUE COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – AVOCADO GREEN COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – ORANGE COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – LILA COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – TEAL BLUE COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – WHITE COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – PINK COLOR
- AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – DUAL COLOR

Basic UDI-DI : 95510152556286R3

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: 2777/10648-06/E05-01. Notified body No. 2777.

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

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – BLUE COLOR	XS	9551015252157
	S	9551015252164
	M	9551015252171
	L	9551015252188
	XL	9551015252195
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – BLACK COLOR	XS	9551015252553
	S	9551015252560
	M	9551015252577
	L	9551015252584
	XL	9551015252591
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – RED COLOR	XS	9551015251853
	S	9551015251860
	M	9551015251877
	L	9551015251884
	XL	9551015251891
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – DARK BLUE COLOR	XS	9551015252256
	S	9551015252263
	M	9551015252270
	L	9551015252287
	XL	9551015252294
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – AVOCADO GREEN COLOR	XS	9551015251952
	S	9551015251969
	M	9551015251976
	L	9551015251983
	XL	9551015251990

PRODUCT DESCRIPTION	SIZE	Device Identifier (DI)
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – ORANGE COLOR	XS	9551015251754
	S	9551015251761
	M	9551015251778
	L	9551015251785
	XL	9551015251792
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – LILA COLOR	XS	9551015251655
	S	9551015251662
	M	9551015251679
	L	9551015251686
	XL	9551015251693
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – TEAL BLUE COLOR	XS	9551015253154
	S	9551015253161
	M	9551015253178
	L	9551015253185
	XL	9551015253192
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – WHITE COLOR	XS	9551015251150
	S	9551015251167
	M	9551015251174
	L	9551015251181
	XL	9551015251198
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – PINK COLOR	XS	9551015251259
	S	9551015251266
	M	9551015251273
	L	9551015251280
	XL	9551015251297
AAMEDIX NITRILE POWDER FREE EXAMINATION GLOVES – DUAL COLOR	XS	9551015253451
	S	9551015253468
	M	9551015253475
	L	9551015253482
	XL	9551015253499

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