



AMST GLOBAL SDN.BHD

Ref No: AMST/ECDOC

EC DECLARATION OF CONFORMITY



Manufacturer Name : AMST Global Sdn. Bhd
Address : No: 9, Jalan bestari, 3a/ku7, Klang, 42100, Selangor, Malaysia
Name of Medical Device : 1- Nitrile Examination Gloves
2- Natural Latex Examination Gloves
Type of products : 1- Powder -Free Natural Latex Examination Gloves
2- Powder Free Nitrile Examination Gloves
Classification: : Class 1 , Non-Sterile
Conformity Route : Self Declaration

We, hereby declare that the devices as listed above meet the applicable provisions of the medical device(s) Directive 93/42/EEC, and the product conforms to EN 455 directive.

Quality Management System : ISO 13485 : 2016

Validity of Declaration from 10-12-2019 till 10-12-2021

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Ms. Puspamalah Palaniandy
Quality Assurance Manager
AMST Global Sdn. Bhd.



Address: No: 9, Jalan bestari, 3a/ku7, Klang, 42100, Selangor, Malaysia
Tel: +60332927171 Website: www.amstglobal.com Email: info@amstglobal.com



AMST GLOBAL SDN.BHD

Ref No: AMST/IOU/NR/NBR

Manufacturer's Instructions for Use

Manufacturer Name : AMST Global Sdn. Bhd
Address : No: 9, Jalan bestari, 3a/ku7, Klang, 42100, Selangor, Malaysia
Name of Medical Device : 1- Natural Latex Examination Gloves, Powder Free
2- Nitrile Examination Gloves, Powder Free
Shelf Life : 5 years from the date of manufacturing

1.1 Preparation for Use: Ensure selection of gloves with correct size. Below is the correct glove size width:

Size	XS	S	M	L	XL
Width Range (in mm)	70±10	80±10	95±10	110±10	120±10

1.2 How to Use:

- Dry hands before donning the gloves.
- Take out the product after checking the package.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- Keep the fingernails short and change the gloves frequently to avoid tearing issues.
- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations.

1.3 Cautions for use:

- The product is for single use only.
- This Product Contains Natural Rubber Latex Which May Cause Allergic reactions.

1.4 Warning:

- Isolated cases of allergic reactions to latex product have been reported. If you experience a reaction to this product, discontinue use immediately and seek medical help.

1.5 Storage Conditions:

- Gloves must be stored in dry conditions.
- Gloves must be stored in cool place and must be kept away from direct sun light.
- Gloves need to be stored far away from any heat generating equipment.

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CERTIFICATE OF COMPLIANCE

We certify that the Technical Documentation of the below mentioned products (Medical Devices Directive 2007 / 47 / EC) According to the Council Directive 93 / 42 / EEC as amended (2007 / 47 / EC)

AMST Global Sdn. Bhd.

No: 9, Jalan bestari, 3a/ku7, Klang, 42100, Selangor,
Malaysia

has been assessed and certified as meeting the requirements of

ISO 13485:2016

For the following products

Manufacturing of Non-sterile Natural Latex
Examination Gloves Powder-Free and Nitrile
Examination Gloves Powder-Free.

This certificate is valid from 17 September 2018 until 17 September
2021 and remains valid subject to satisfactory surveillance audits.



Deutsche Accreditation Board

Otto-Hahn-Ring 6, D-81739 Muenchen, Germany

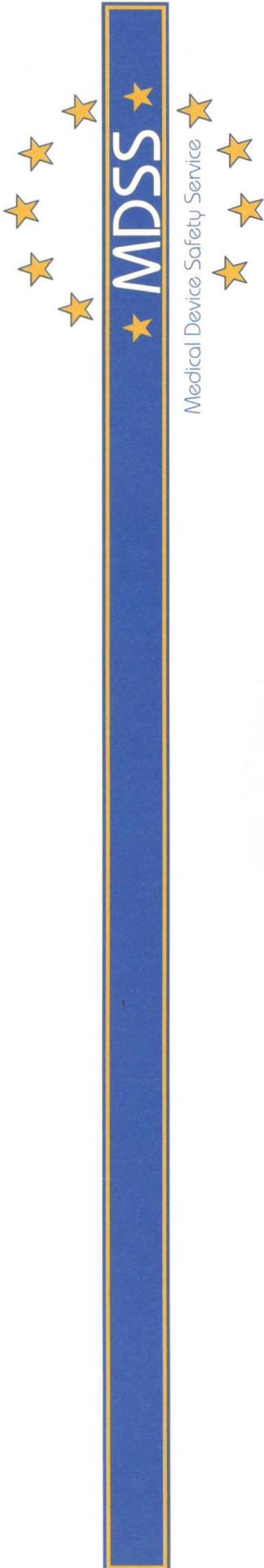
E-mail: markglobal@dmail.com Website: www.dabaccreditation.com

The validity of this certificate is contingent upon the condition that the client has understood & shall abide by contract agreement, certification agreement for certification services and logo rules as given on our Website: www.dabaccreditation.com. The client is request to check the above certificate details at our above mentioned Website and also on www.markglobal.org under the heading of Register & Sub heading of certified organization by entering their certificate number and inform us in case of any discrepancy at our above email id.


Authorized Signatory

EUROPEAN CERTIFYING ORGANIZATION

Certificate of CE-Registration



This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

AMST GLOBAL SDN BHD
No: 9, Jalan bestari, 3a/ku7, Klang, 42100,
Selangor, Malaysia

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated December 10, 2018

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2018 / 12 / 10 Certificate
number: **501094**

Elsa Villanueva-Möller

Elsa Villanueva-Möller
Director of Administration / Business Development
MDSS GmbH

Annex A dated December 10, 2018

Manufacturer: AMST GLOBAL SDN.BHD.

Number	Medical device name	Class**	Rule	Catalogue Reference number	Short Description and intended use	GMDN Code**
1	Natural Latex Examination Gloves, Powder -Free	I Non-Sterile	5	NIL	Disposable Examination Glove for single use.	47172
2	Nitrile Examination Gloves, Powder Free	I Non-Sterile	5	NIL	Disposable Examination Glove for single use.	56286