

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000349275-PA-NA-IND

Project No.:  
PRJC-188486-2009-PRC-IND

Valid Until:  
27 May2024

This is to certify that the quality system of:

### AMAZING RUBBER PRODUCTS PVT LTD

Plot No:14C, CSEZ KAKKANAD, COCHIN – 682037.Kerala, India

For design, production and final product inspection/testing of:

**Sterile Latex Surgical Gloves, Sterile Latex Examination  
Gloves and Sterile Synthetic Examination Gloves**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE  
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
Høvik, 03 July 2020



For:  
DNV GL PRESAFE AS  
Notified Body No.: 2460

**Alexandra Poulsson**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



Certificate No.:  
10000349275-PA-NA-IND

Project No.:  
PRJC-188486-2009-PRC-IND

Valid Until:  
27 May2024

**Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	03 July 2020

Products covered by this Certificate:

Product Description	Product Name	Class
1. Sterile Natural Rubber Latex Surgical Gloves	Powdered Size: 5½, 6, 6½, 7, 7½, 8, 8½, 9 Brand: AMCARE, AMAZING, SAFE N CARE	IIa
	Powderfree Size: 5½, 6, 6½, 7, 7½, 8, 8½, 9 Brand: AMCARE +, AMAZING +, SAFE N CARE +	IIa
2. Sterile Natural Rubber Latex Examination Gloves	Powdered Size: Extra small (6.0, 6.5), small (7.0), Unisize (7.5), Medium (8) Large 8.5 and extra large 9.0 Brand: AMAZING	Is
	Powderfree Size: Extra small ( 6.0, 6.5), small (7.0), Unisize(7.5), Medium (8) Large 8.5 and extra large 9.0 Brand: AMAZING +	Is
3. Sterile Nitrile Examination Gloves - Synthetic latex	Powdered Size: Extra small (6.0, 6.5), small (7.0), Unisize (7.5), Medium (8) Large 8.5 and extra large 9.0 Brand: AMAZING	Is
	Powderfree Size: Extra small (6.0, 6.5), small (7.0), Unisize (7.5), Medium (8) Large 8.5 and extra large 9.0 Brand: AMAZING +	Is

The complete list of devices is filed with the Notified Body

Certificate No.:  
10000349275-PA-NA-IND

Project No.:  
PRJC-188486-2009-PRC-IND

Valid Until:  
27 May2024

**Sites covered by this certificate**

Site Name	Address
AMAZING RUBBER PRODUCTS PVT. LTD.	Plot No:14C, CSEZ KAKKANAD, COCHIN – 682037.Kerala, India

**EU Representative**

EUROPECERT located in Alsstrasse 97, 41063 Mönchengladbach, Germany.  
Phone: +49 (0) 2161 990 8831 Email: [support@europecert.eu](mailto:support@europecert.eu)  
website: [www.europecert.eu](http://www.europecert.eu)

**Terms and conditions**

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

**Conformity declaration and marking of product**

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate