EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C556189	06 February 2025	05 February 2030

This is to certify that the quality system of

St.Marys Rubbers Pvt. Ltd.

XVII/401A, Thottamkavala, Vizhikkathode, Koovappally P.O,
Kanjirappally, Kottayam- 686 518,Kerala, India.

SRN: IN-MF-000008817

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

Sterile Latex Surgical Gloves Powdered, Sterile Latex Surgical Gloves Powder Free (Polymer coated), Sterile Latex Gynaecological Gloves Powdered, Sterile Latex Gynaecological Gloves Powder Free (Polymer coated), Sterile Latex Examination Powdered, Sterile Latex Examination Powder Free (Polymer Coated)

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 12 June 2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2744665	06 February 2025
1.0	New Brands added in products - Sterile Latex Surgical Gloves Powdered (**Integrity, LOGITOUCH, Elektro, MG OriginPharma, Antarcglove**), Sterile Latex Surgical Gloves Powder Free (**P&Q, Integrity, LOGITOUCH, MG OriginPharma, Dr.Kelly, Antarcglove**), Sterile Latex Gynaecological Gloves Powder Free (**P&Q, Integrity, LOGITOUCH, Antarcglove**)	3332642	12 June 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Sterile Latex Surgical Gloves Powdered	Sterile Latex Surgical Gloves Powdered: Size: 5.5 to 9.0 Brand Names: Medismart, Medistar, Mediten, One Glove, PROSURJ, PROTEX, Medismart Premium, MPL Medismart, Mediagni, Krutex, BROMED, CoreMed, IDA, Serix Explorer, Kaizmed, MAJORIS, **Integrity, LOGITOUCH, Elektro, MG OriginPharma, Antarcglove**	IIa
Sterile Latex Surgical Gloves Powder Free (Polymer coated)	Sterile Latex Surgical Gloves Powder Free (Polymer coated): Size: 5.5 to 9.0. Brand Names: Medismart+, Mediten Plus, One Glove Plus, NEOMEX, POLYSEM, Medismart Premium Plus, Protex PF, Mediagni PF, Krutex, BROMED, CoreMed , IDA, SERIX EXPLORER PLUS, Dr.Mayer, Kaizmed, EUROGLOVES-QLE, Medismart Premium Plus LOW PRO, **P&Q, Integrity, LOGITOUCH, MG OriginPharma, Dr.Kelly, Antarcglove**	IIa
Sterile Latex Gynaecological Gloves Powdered	Sterile Latex Gynaecological Gloves Powdered: Size: 6.5 , 7.5 , 8.5 length: 350 mm, 400 mm, 450mm Brand Name: Medismart	IIa
Sterile Latex Gynaecological Gloves Powder Free (Polymer coated)	Sterile Latex Gynaecological Gloves Powder Free (Polymer coated): Size: 6.5 , 7.5 , 8.5 length: 350 mm, 400 mm, 450mm Brand Name: Medismart+, SERIX EXPLORER OBGYN, CoreMed, One Glove Plus, **P&Q, Integrity, LOGITOUCH, Antarcglove**	IIa

Sterile Latex Examination Powdered	Sterile Latex Examination Powdered Size: XS, S, M, L, XL Brand Name: Smartex, Protex, SETINO	Is
Sterile Latex Examination Powder Free (Polymer Coated)	Sterile Latex Examination Powder Free (Polymer Coated) Size: XS, S, M, L, XL Brand Name: Smartex Plus	Is

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: N/Ap

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
St.Marys Rubbers Pvt. Ltd.	XVII/401A, Thottamkavala, Vizhikkathode, Koovappally P.O, Kanjirappally, Kottayam- 686 518, Kerala, India
St.Marys Rubbers Pvt. Ltd.	XVII/401 B, Thottamkavala, Vizhikkathode, Koovappally P.O, Kanjirappally, Kottayam -686518, Kerala, India
St.Marys Rubbers Pvt. Ltd.	XVII/401 O, Thottamkavala, Vizhikkathode, Koovappally P.O, Kanjirappally, Kottayam -686518, Kerala, India

EU Representative
Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.