

Technical Sheet

Product: Sterile Latex Surgical Gloves For Gynaecological & Obstetrical Use
Manufacturer: ST MARYS RUBBERS PVT. LTD.
EC-REP: Emergo Europe BV



Latex Powder Free Gynaecological Sterile Gloves (Medismart)

DESCRIPTION

- Gloves compounded primarily from natural rubber latex (Type-1).
- Powder free gloves coated with unique blend of polymer to provide excellent donning capability.
- Creamy white to pale yellow in color (Natural).
- Excellent barrier protection due to its extra length preventing cross contamination.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- EO sterilized

DESIGN & FEATURES:

- Anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat
- The cuff shall fit closely without being constrictive and it shall not roll back or ruckle while in use.
- Anatomically shaped with micro rough surface in palm and finger area.
- Products have shelf-life of 3 years from the date of manufacturing.
- Each glove has non- detectable level of chemical residue.
- Sterilized by validated procedure as per ISO 11135:2014 which maintains sterility assurance level is 10-6
- Passes Viral Penetration test as per ASTM F 1671.
- Biologically compatible as per ISO 10993-Part 5 ,7,10 & 11.
- Passes Bacterial Endotoxin test as per EN 455-3:2015.
- Manufactured in clean environment to reduce bio burden level prior to sterilization.

CHARACTERISTICS	BEFORE AGING	AFTER AGING
	ASTM D 3577:2019, IS 13422:1992	
Tensile Strength (Mpa)	24 Min	18 Min
Ultimate Elongation (%)	750 Min	560 Min
Stress at 500% Elongation (Mpa)	5.5 Max	N/A
Minimum Force at Break (N)	9.0 Min	9.0 Min
EN 455-2:2009 + A2:2013		

DIMENSIONS (ASTM D 3577:2019, EN 455-2:2009+A2:2013, IS 13422:1992)

Size	Length (mm)	Width (mm)	Weight (g)	Thickness Cuff	Thickness Palm	Thickness Finger
6.5	400	83 ± 6	25.2 ±0.6	0,12 mm	0,16 mm	0,18 mm
7.5		95 ± 6	27.6 ±0.6			
8.5		108 ± 6	31.2 ±0.6			

Characteristics	Freedom from holes	Physical Dimensions	Physical Properties	Extractable Protein Content	Powder amount	Sterility
Inspection Level	G-1	S2	S2	N=5	S2	S2
AQL	0.65	4.0	4.0	-	1.5	1.5

Packing	Number of pairs
Double Sterile Packaging	1 Pair (1 Left + 1 Right)
BOX	25 Pairs
BAX	200 Pairs (8 Boxes)

Latex Powder Free Gynaecological Sterile Gloves (Medismart)



ST MARYS RUBBERS PRIVATE LIMITED
Reg Office Address: XVII/401A, Thottamkavala
Vizhikkathode, Koovappally P.O.
Kanjirappally, Kottayam
Kerala - 686518, India
Phone: +91 (0) 4828 252277
+91 9446 076 270
Email: cs@stmarysrubbers.com
Web: www.stmarysrubbers.com
CIN: U25199KL2002PTC015698

Doc No: F/QA/32
Issue No, Date: 01, 11.09.2018
Rev No, Date: 05, 08.10.2021

DECLARATION OF CONFORMITY

Application of European Union Council Directive 93/42/EEC as amended by 2007/47/EC

Manufacturer : St Marys Rubbers Pvt. Ltd.
XVII/401A, Thottamkavala, Vizhikkathode, Koovappally PO,
Kanjirappally, Kottayam - 686518, India
SRN : IN-MF-000008817
European Union Authorized Representative : Emergo Europe BV, Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SRN : NL-AR-000000116
Product : Sterile latex gynaecological gloves powder free (polymer coated)
Basic UDI-DI : 8908004935LG0193
Brand : Medismart +
Batch No : 2021013
Size : 6.5, 7.5, 8.5
Device Classification : Class Ila as per Rule 6, Annex IX of Council Directive 93/42/EEC
Conformity Assessment Route : Article 11.3(a) and Annex II excluding section 4
Standards Applied : EN ISO 13485 : 2016, EN ISO 14971 : 2012, EN455-1 : 2000, EN 455-2:2009+A2:2013
EN 455-3:2006, EN 455-4 : 2009, EN ISO 15223-1:2016, EN ISO 10993-1 : 2009/AC:2010,
EN ISO 10993-5 : 2009, EN ISO 10993-7 : 2008, ISO 10993-10 : 2010, ISO 11135 :2014,
EN ISO 11138-2: 2009, EN ISO 11737-1: 2006/ AC:2009, EN ISO 11737-2: 2009,
EN 1041: 2008, EN ISO 11607-1:2009, EN ISO 11607-2 :2006, ISO 10993-11:2017,
EN 62366:2008
Applicable Guidance Documents : MEDDEV 2.5/9 Rev 1, MDD 93/42/EEC as amended, MEDDEV 2.7.1 Rev 4,
MEDDEV 2.4/1 Rev 9, MEDDEV 2.12/2 Rev 2, MDR 2017/745
Notified Body name & address : DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway
Notified Body : 2460
EC Certificate No. : 9877-2017-CE-IND-NA-PS Rev. 4.0
Date & Place of Issue : 26 April 2021, Hovik
Validity Date : 27 May 2024

We declare under our sole responsibility that the above mentioned product complies with the essential requirements of EC Directive 93/42/EEC, Annex IX, Class Ila, Rule 6. All Prior amendments are and as transposed into national laws.

Signed on the behalf of the manufacturer:

Anjali Vinod
Manager QA

Date: 21.12.2021
Place: Kanjirappally



medismart | medismart+ | medistar | medismart | medismart | Soteria | medismart |
PREMIUM QUALITY LATEX SURGICAL GYNAECOLOGICAL AND EXAMINATION GLOVES 04697



Report No. : CH:TX:1142019075

TEST REPORT

DATE : 17/07/2020

ST MARYS RUBBERS PRIVATE LIMITED
GLOVES DIVISION, XVII-401A, THOTTAM KAVALA, VIZHIKKATHODE
Kottayam-686158

IN
CONTACT PERSON : ANJALI VINOD

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :
SAMPLE DESCRIPTION

GLOVES
STERILE LATEX GYNAECOLOGICAL GLOVES POWDER FREE, (POLYMER COATED)
MANUFACTURING DATE: 2020/06
STERILISATION DATE: 2020/06
EXPIRY DATE: 2023/05
820019
MEDISMART +

BATCH NO.
BRAND
PHOTO APPENDIX.



SAMPLE RECD ON
RESULT SUMMARY

07/07/2020

TESTING PERIOD : 07/07/2020 - 17/07/2020

TESTS	PASS	FAIL	REMARKS
EXTRACTABLE PROTEIN CONTENT			REFER RESULTS.

Per pro SGS India Private Ltd.

K. Pachaiyappan
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

RESULTS

MEDICAL GLOVES FOR SINGLE USE - EXTRACTABLE PROTEIN CONTENT
EN 455-3:2006

PROTEIN CONTENT 19.7 µg/g

Detection Limit = 10 µg/g

***** End of Report*****

JOE No : 2042810350

4506979

Page 1 of 2

Control No: 1142521010

This document is issued by the Company under its General Conditions of Service printed overleaf or available on request and accessible at http://www.sgs.com/terms_and_conditions.htm and Terms and Conditions for electronic documents www.sgs.com/terms_e-document.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. This document cannot be reproduced except in full, without prior approval of the Company.

SGS India Pvt. Ltd. Consumer and Retail Testing Laboratory, 28 B/1(SP), 28 B/2(SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai - 600 058, India
t: (91-44) 8808 1000

Member of the SGS Group (SGS SA)

Latex Powder Free Gynaecological Sterile Gloves (Medismart)



EC CERTIFICATE Full Quality Assurance System

Certificate No. 9877:2017-CE-IND-NA-PS Rev. 4.0 Project No. PRUC-529657-2015-PRC-IND Valid Until: 27-May-2024

This is to certify that the quality system of:

ST MARYS RUBBERS PVT. LTD.

XVII/401A, THOTTAMKAVALA, VIZHIKKATHODE, KOOVAPPALLY PO,
KANJIRAPPALLY, KOTTAYAM - 686 518, INDIA

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

STERILE LATEX SURGICAL, EXAMINATION & GYNAECOLOGICAL 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:
Havik, 26 April 2021



For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Alessandra Rinna
Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Havik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-1-MDD-Q2, rev 0



Certificate No. 9877:2017-CE-IND-NA-PS Rev. 4.0
Place and date: Havik, 26 April 2021

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	Replaces certificate 7512-2015-CE-IND-NA Rev 1.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-26
1.0	Extension in scope – Brand Addition & ER Address Change	2019-04-29
2.0	Address change - From previous registered address to address of the manufacturing site	2020-06-19
3.0	Brand addition (in bold)	2021-02-04
4.0	Recertification	26 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Latex Surgical Gloves	Sterile Surgical Latex Gloves Powdered Brands: Sterile Surgical Latex Gloves Powdered, Medismart, Medistar, Mediten, One Glove, PRO-SURJ, PROTEX, Medismart Premium, MPL Medismart, Mediagni, Krutex	Ila
	Sterile Surgical Latex Gloves Powder Free (polymer coated) brands: Sterile Surgical Gloves Powder Free (polymer coated), Medismart +, Mediten Plus, One Glove Plus, NEOMEX, POLYSEM, Medismart Premium Plus, Protex PF, Mediagni PF, Krutex	Ila
Latex Examination Gloves	Sterile Examination Powdered Models: Smartex	Is
Latex Gynaecological gloves	Sterile Latex Gynaecological Powdered models: Medismart	Ila
	Sterile Latex Gynaecological Powder free (Polymer coated) models : Medismart +	

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Havik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-1-MDD-Q2, rev 0

Page: 2 of 4



Certificate No. 9877:2017-CE-IND-NA-PS Rev. 4.0
Place and date: Havik, 26 April 2021

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 PO, KANJIRAPPALLY, KOTTAYAM - 686 518, INDIA

EU Representative

Emergo Europe BV, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Havik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-1-MDD-Q2, rev 0

Page: 3 of 4

Latex Powder Free Gynaecological Sterile Gloves (Medismart)



TEST REPORT



Sample ID No.	TAS/20-21/1276	ULR No.	TC54102000000173F
Sample received Date	03/07/2020	Test Report No.	TAS/REP/1528
Analysis start Date	03/07/2020	Report Date	21/07/2020
Analysis completed Date	21/07/2020	Report type	Original
Customer Ref No.	Your TRF dated 03/07/2020	Total Page(s)	1 of 1
Name of the customer	M/s. ST. MARY'S RUBBERS PVT. LTD		
Address	XVII/401 A, Thottamkavala, Vizhikkathode, Koovappally P.O., Kanjirappally, Kottayam District - Kerala State - 686 518, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Gynaecological Gloves, Powder Free, Polymer coated	Test Method/Specification	EN 455 - 1: 2000, EN 455-2& ASTM D 3577-19
Batch No	820019	Size	7.5
Quantity received	60 Pairs	Mfg. Date	2020/06
Brand	Medismart +	Exp. Date	2023/05
Mfg. by	M/s. St. Mary's Rubbers Pvt. Ltd., Kottayam.		

TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits	Results Obtained	Sample Status
			Min. Max.		
1	Dimension				
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270 --	Median : 445	Passes the test
	Width (mm)		90 100	Median : 95.0	Passes the test
2	Physical Properties				
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0 --	Median : 15.9	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0 --	Median : 13.9	Passes the test
3	Freedom from Holes	EN455-1:2000	-- --	No Holes found	Passes the test
4	Powder Residue (mg/dm²)	ASTM D 3577-19	-- 2.0	Average: 0.60	Passes the test
5	Sterility test	EP 9.0	No evidence of microbial growth	No growth	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455- 1:2000, EN 455-2 & ASTM D 3577-19 specifications with respect to the above tests only.

Abbreviations: EN : European Standard; mm : European Pharmacopoeia; ASTM : American Society for Testing and Materials International; Millimeter; mg : milligram;

Reported by: K.SENTHILKUMAR, TECHNICAL MANAGER
 Reported by: M.V. TAMIL VANNAN, DY. MANAGER - MICROBIOLOGY
 Approved by: M. MAHENDRAN, QUALITY MANAGER

- * This test report shall not be reproduced either in full or in part, without written approval of the laboratory. *
- * The test results in this report refer only to the sample tested in the laboratory and the sample submitted by the party *

NABL Accredited Laboratory vide cert. No: TC-5410 valid upto 30/03/2021



TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,
 R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,
 Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.

Ph: 044-22731006, Email: customercare@trustingroup.in, web: www.trustingroup.in



MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 10000356864-PA-NA-IND
 Project No.: PRJC-529957-2015-PRC-IND
 Initial Certification Date: 20 April 2020
 Valid Until: 19 April 2023

This is to certify that the management system of:

ST.MARYS RUBBERS PVT LTD

XVII/401A, THOTTAMKAVALA, VIZHIKKATHODE, KOOVAPPALLY PO, KANJIRAPPALLY, KOTTAYAM - 686 518, INDIA.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

MANUFACTURING, DISTRIBUTION & SALES OF STERILE & NON-STERILE, POWDERED AND POWDER FREE LATEX SURGICAL, GYNAECOLOGICAL AND EXAMINATION GLOVES.

Place and date:
 Havik, 20 April 2020



For:
 DNV GL PRESAFE AS

Eugenie Winger Husebye
 Eugenie Winger Husebye

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



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
 ACCREDITED UNIT: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Havik, Norway - Registered Enterprise No: NO 997 067 401. PVA.

MSD-CP-243-A, Ver. 1.0

Page 1 of 1

Thank you!



comenzi@medplaza.ro
office@medplaza.ro

www.medplaza.ro
0316.30.66.90