

Technical sheet

Product: Sterile Latex Surgical Gloves Powder Free

Manufacturer: ST MARYS RUBBERS PVT. LTD.

EC-REP: Emergo Europe BV



Sterile Latex Surgical Gloves Powder Free (Medismart premium plus)

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 colour (Natural colour).
- 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.
- The physical properties, dimension and tensile strength of the material is as per European CE/USFDA standards (EN 455, ASTM D 3577 and IS 13422).
- Anatomically shaped with micro rough surface in inner palm and in inner part of finger area which provides good grip at wrist and in curved fingers
- Products have shelf-life of 5 years from the date of manufacturing.
- Each glove has non-detectable levels of chemical residue.
- Sterilized by validated process cycle (ISO 11135:2014).
- Passes Viral Penetration test as per ASTM F 1671.
- The Sterility Assurance Level (SAL) is 10^{-6} .
- Biologically compatible as per ISO 10993-Part 5, 7, 10 & 11.
- Non-toxic and non- irritant.
- Size of the gloves is embossed on the palm area.

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 Fingers
6.0	275	76 ± 6	15.9 ± 0.6	0.11 mm	0.14 mm	0.16 mm
6.5		83 ± 6	18.4 ± 0.6			
7.0		89 ± 6	19.2 ± 0.6			
7.5		95 ± 6	20.0 ± 0.6			
8.0		102 ± 6	21.3 ± 0.6			
8.5	280	108 ± 6	23.0 ± 0.6			

Characteristics	Freedom from holes	Physical Dimensions	Physical Properties	Extractable Protein Content	Powder amount	Sterility
Inspection Level	G-1	S2	S2	N=3	N=3	Standard
AQL	0.65	4.0	4.0	-	-	-

Packing	Number of pairs
Double Sterile Packaging	1 Pair (1 Left+ 1 Right)
BOX	50 Pairs
BAX	500 pairs (10 Boxes)

Sterile Latex Surgical Gloves Powder Free (Medismart premium plus)



ST MARYS RUBBERS PRIVATE LIMITED
Reg. Office Address: XVII/401A, Thottamkavala
Vizhikkathode, Koovappally P.O.
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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: 04, 30.11.2020

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

European Union Authorized Representative : Emergo Europe BV, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Product : Sterile surgical latex gloves-powder free (polymer coated)

Brand : Medismart +

Batch No :
Size : 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

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, EN ISO
10993-5 : 2009, EN ISO 10993-7 : 2008, ISO 10993-10 : 2010, ISO 11135-1:2014, EN ISO
11138-2 : 2009, EN ISO 11737-1 : 2006, EN ISO 11737-2 : 2009, EN ISO 11607-1 : 2009,
EN ISO 11607-2 :2006, EN 1041:2008, 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, ME DDEV 2.12/2 Rev 2, NB- MED /2.12/Rec 1

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
This Declaration of Conformity is valid until 27 May 2024, EC certificate validity date.

Date : 23.09.2021
Place: Kanjirappally





Authorized Signatory


Anjali Vinod
Manager QA

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

03483


Sterile Latex Surgical Gloves Powder Free (Medismart premium plus)



TEST REPORT


Report No. : CH:TX:1142019073

DATE : 17/07/2020



ST MARYS RUBBERS PRIVATE LIMITED
GLOVES DIVISION, XVII-401A, THOTTAM KAVALA, VIZHIKATHODE
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 SURGICAL GLOVES POWDER FREE POLYMER COATED
MANUFACTURING DATE: 2020/06
STERILISATION DATE: 2020/06
EXPIRY DATE: 2023/06
BATCH NO. 820021
BRAND MEDISMART +
PHOTO APPENDIX.



SAMPLE RECD ON 07/07/2020
RESULT SUMMARY

TESTING PERIOD : 07/07/2020 - 15/07/2020



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



TEST REPORT

Report No. : CH:TX:1142019073

DATE : 17/07/2020



RESULTS

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

PROTEIN CONTENT 24.5 µg/g

Detection Limit = 10 µg/g

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

JOE No. : 2042610349 456069 Page 1 of 2 Control No. 1142521011
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Sterile Latex Surgical Gloves Powder Free (Medismart premium plus)



EC CERTIFICATE Full Quality Assurance System

Certificate No. 9877-2017-CE-IND-NA-PS Rev. 4.0 Project No.: PRJC-529957-2015-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



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.

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ICP-4-5-1-MDD-02, rev 0

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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-02, rev 0

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Sterile Latex Surgical Gloves Powder Free (Medismart premium plus)

DNV·GL

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 MVA.

MSD-CP-243-A, Ver. 1.0

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TEST REPORT

Sample ID No.	TAS/18-19/1293	ULR No	TC541018000000088P
Sample received Date	02/02/2019	Test Report No.	TAS/REP/0529
Analysis start Date	02/02/2019	Report Date	15/02/2019
Analysis completed Date	15/02/2019	Report type	Original
Customer Ref No.	Your TRF dated 02/02/2019	Total Page(s)	1 of 1
Name of the customer	M/s. ST. MARY'S RUBBERS PVT. LTD		
Address	XVII, 401A, Thottam Kavala, Vizhikkathode, Koovalpally P.O., Kanjirappally, Kottayam District, Kerala State - 686 518, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Surgical Gloves (Powder Free)	Test Method/ Specification	EN 455-1: 2000/ EN 455-2 & 3 : 2015
Batch No	B19004	Size	7.5
Quantity received	30 Pairs	Mfg. Date	2019/01
Brand	MEDISMART PLUS	Exp. Date	2021/12
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	EN 455-2:2015 (Clause 4.2 & 4.3)	270	—	Median : 289	Passes the test
	Length (mm)		90	100	Median : 97	Passes the test
2	Physical Properties - Before Ageing	EN 455-2:2015 (Clause 5.2)	9.0	—	Median : 13.0	Passes the test
	Force at Break (N)		9.0	—	Median : 11.0	Passes the test
3	Physical Properties - After Ageing @ 70°C for 168 Hours	EN 455-2:2015 (Clause 5.3)	9.0	—	Median : 11.0	Passes the test
	Force at Break (N)		9.0	—	Median : 11.0	Passes the test
4	*Powder Content (mg/glove)	EN 455-3 (Clause 4.4)	—	2.0	1.03	Passes the test
5	Freedom from Holes	EN 455-1:2000	—	—	No holes found	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455-1:2000 & EN 455-2 & 3 : 2015 specifications with respect to the above tests only.

Note: * Parameter is not covered under NABL scope.

Abbreviations: EN : European Standard; mm: Milli meter; mg : Milli gram; N : Newton;

...End of Report...

Reported by

K.SENTHILAKUMAR
TECHNICAL MANAGER

Approved by

M. MAHENDRAN
QUALITY MANAGER

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* 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 30/03/2019

TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,
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Thank you!



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