Technical sheet

Product: Sterile Latex Surgical Gloves Powdered
Manufacturer: ST MARYS RUBBERS PVT. LTD.
EC-REP: Emergo Europe BV

comenzi@medplaza.ro
office@medplaza.ro

www.medplaza.ro
0316.30.66.90

Sterile Latex Surgical Gloves Powdered *(Medismart)*

Description

- Gloves compounded primarily from natural rubber latex (Type-1).
- 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 laying flat.
- Lightly powdered with modified absorbable Corn Starch USP.
- 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 5 years from the date of manufacturing.
- Each glove has non-detectable levels of chemical residue.
- Sterilized by validated process cycle as per 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.
- Nontoxic, non-irritant and non-pyrogenic.

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) EN 455-2:2009 + A2:2013	9.0 Min	9.0 Min

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	265	76 ± 6	14.0 ±0.6	0.10 mm	0.10 mm	0.10 mm
6.5		83 ± 6	15.8 ±0.6			
7.0	270	89 ± 6	16.8 ±0.6			
7.5		95 ± 6	18.0 ±0.6			
8.0		102 ± 6	19.4 ±0.6			
8.5	280	108 ± 6	20.8 ±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)

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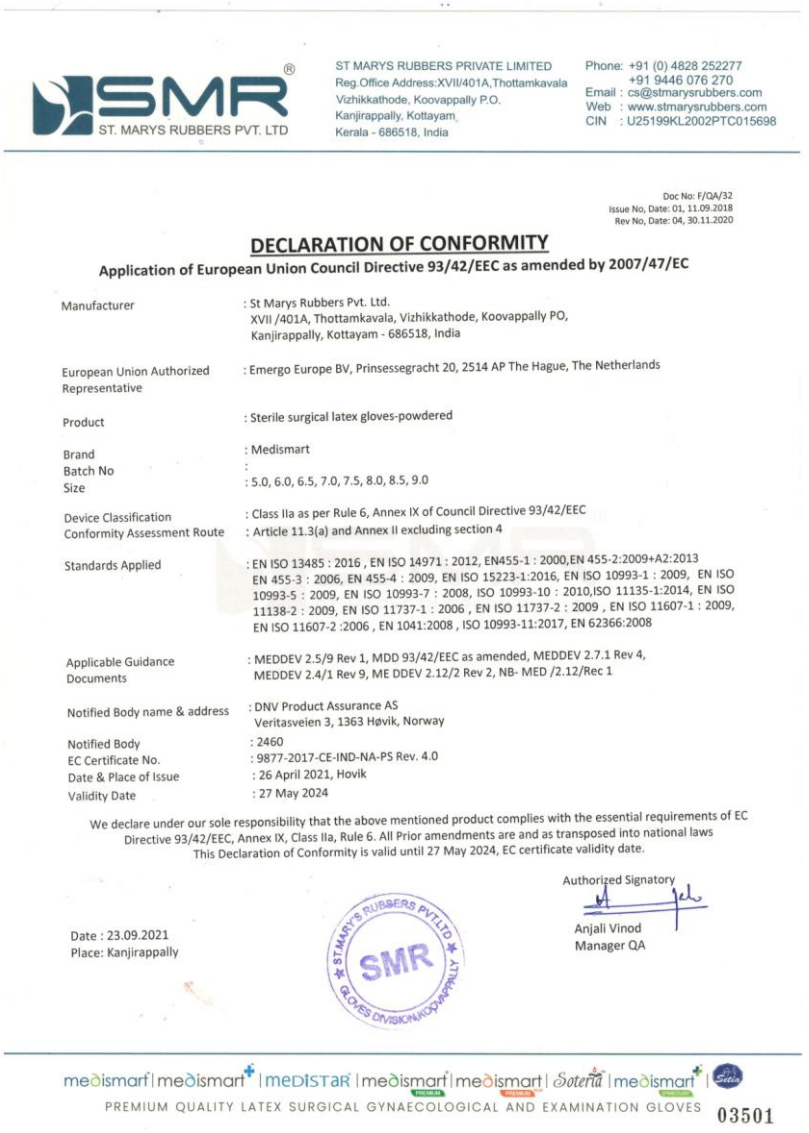

SMR®
ST. MARYS RUBBERS PVT. LTD

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: 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-powdered
Brand	: Medismart
Batch No	:
Size	: 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Device Classification	: Class IIa 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 IIa, 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.

Authorized Signatory

Anjali Vinod
Manager QA

Date : 23.09.2021
Place: Kanjirappally

ST.MARY'S RUBBERS PVT.LTD SMR GLOVES DIVISION,KOOVAPPALLY

medismart | medismart | MEDISTAR | medismart | medismart | Soteria | medismart

PREMIUM QUALITY LATEX SURGICAL GYNAECOLOGICAL AND EXAMINATION GLOVES

03501

Sterile Latex Surgical Gloves Powdered *(Medismart)*

SGS

TC-6176

TEST REPORT

Report No. : CH:TX:1142019077 **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 SURGICAL GOLVES POWDERED
MANUFACTURING DATE: 2020/06
STERILISATION DATE: 2020/06
EXPIRY DATE: 2023/05
BATCH NO. 820022
BRAND MEDISMART
PHOTO APPENDIX.

SAMPLE RECD ON 07/07/2020 **TESTING PERIOD :** 07/07/2020 - 17/07/2020

RESULT SUMMARY

TESTS	PASS	FAIL	REMARKS
EXTRACTABLE PROTEIN CONTENT			REFER RESULTS.

Per pro SGS India Private Ltd.

R. GANESAN
SECTION INCHARGE
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

SGS

TC-6176

TEST REPORT

Report No. : CH:TX:1142019077 **DATE : 17/07/2020**

RESULTS

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

PROTEIN CONTENT	25.6 µg/g

Detection Limit = 10 µg/g

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

Sterile Latex Surgical Gloves Powdered *(Medismart)*

DNV

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 excludi 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, 26 April 2021

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

Alessandra Rinna
Assessor

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**	IIa
	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**	IIa
Latex Examination Gloves	Sterile Examination Powdered Models: Smartex	Is
Latex Gynaecological gloves	Sterile Latex Gynaecological Powdered models: Medismart Sterile Latex Gynaecological Powder free (Polymer coated) models : Medismart +	IIa

DNV
Certificate No. 9877-2017-CE-IND-NA-PS Rev. 4.0
Place and date: Høvik, 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

Sterile Latex Surgical Gloves Powdered *(Medismart)*

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:
Høvik, 20 April 2020

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS
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 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

MSD-CP-243-A, Ver. 1.0

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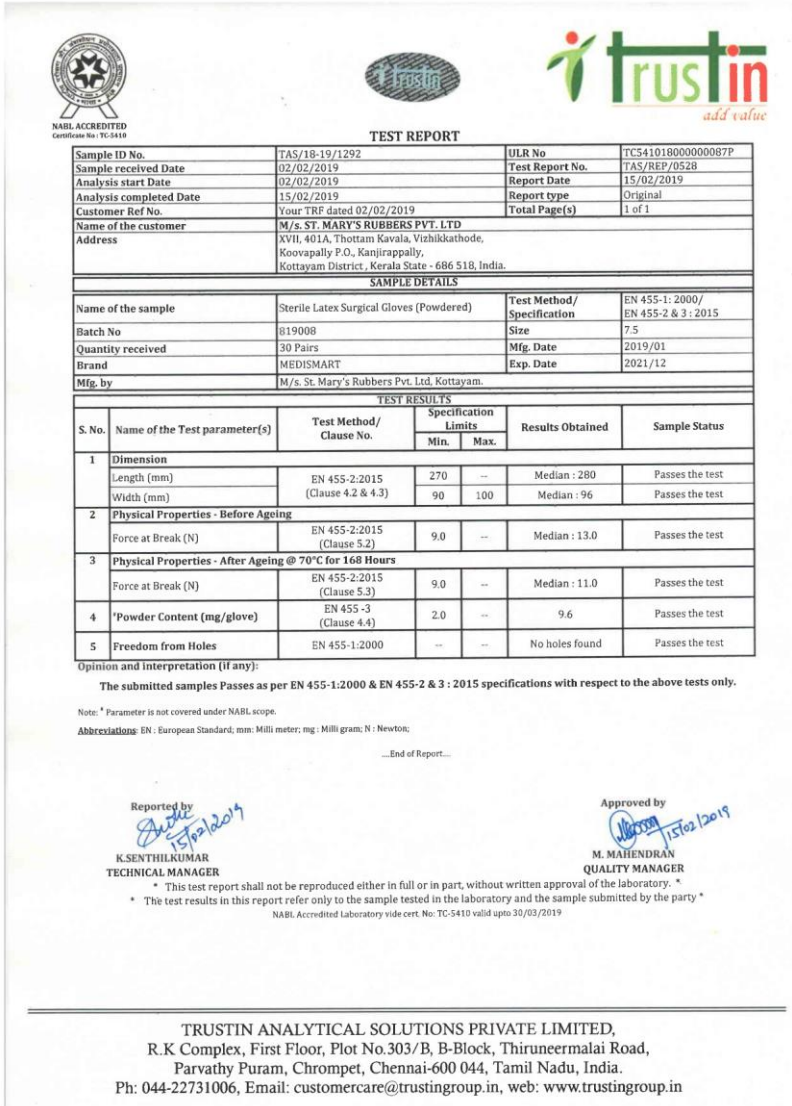

NABL ACCREDITED
Certificate No : TC-5410

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add value

TEST REPORT

Sample ID No.	TAS/18-19/1292	**ULR No**	TC541018000000087P
Sample received Date	02/02/2019	**Test Report No.**	TAS/REP/0528
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, Koovapally P.O., Kanjirappally, Kottayam District , Kerala State - 686 518, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Surgical Gloves (Powdered)	**Test Method/ Specification**	EN 455-1: 2000/ EN 455-2 & 3 : 2015
Batch No	819008	**Size**	7.5
Quantity received	30 Pairs	**Mfg. Date**	2019/01
Brand	MEDISMART	**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 Min.	Specification Limits Max.	Results Obtained	Sample Status
1	**Dimension**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 280	Passes the test
	Width (mm)		90	100	Median : 96	Passes the test
2	**Physical Properties - Before Ageing**					
	Force at Break (N)	EN 455-2:2015 (Clause 5.2)	9.0	--	Median : 13.0	Passes the test
3	**Physical Properties - After Ageing @ 70°C for 168 Hours**					
	Force at Break (N)	EN 455-2:2015 (Clause 5.3)	9.0	--	Median : 11.0	Passes the test
4	*Powder Content (mg/glove)	EN 455 -3 (Clause 4.4)	2.0	--	9.6	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
15/02/2019
K.SENTHILKUMAR
TECHNICAL MANAGER

Approved by
15/02/2019
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 30/03/2019

TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,
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Thank you!

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