1.0 STERILE LATEX SURGICAL GLOVES POWDER FREE (POLYMER COATED) (STERILE POWDER FREE – TYPE 1)

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.

INTDENDED USE:

- Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn on the hand of surgeon and healthcare personnel to prevent cross-contamination between healthcare personnel and patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive surgery.

GENERAL INSTRUCTIONS:

- Store the gloves in cool, dry place and away from direct sun light.
- Sterile Gloves for single use only. Sterile until package is opened or damaged.
- For transient use (normally intended for continuous use for less than 60 minutes)
- This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses in some individuals.
- Reuse of gloves may cause infection, allergic reaction and poor barrier protection.
- Dispose after use as per hospital policies or country's regulatory norms.

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

Size	Length (mm)	Palm Width (mm)	Thickness (in mm)					
			Cuff (Min)		Palm (Min)		Finger (Min)	
	Min	Specification	Standard	SMR	Standard	SMR	Standard	SMR
5½	250	70 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
6	275	76 ± 6						
6 ½		83 ± 6						
7	275	89 ± 6						
7 ½		95 ± 6						
8		102 ± 6						
8 ½	280	108 ± 6						
9		114 ± 6						

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.
ASTM D 3577:2019, IS 13422:1992		
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation (%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5.5	NA
EN 455-2:2009+A2:2013		
Minimum force at break	9.0 N	9.0 N

Aqueous extractable protein content **(As per standards ASTM D 3577:2019)**	< 200 μg/dm^2 – Test method ASTM D 5712-15 (2020)
Powder content **(As per standards ASTM D 3577:2019)**	< 2 mg / glove– Test method ASTM D 6124-06 (2017)
Sterilization	Ethylene Oxide
Sterility	Shall pass Sterility test as per IP /USP / EU Pharmacopeia
Labeling	Shall comply with government, regulatory and customer requirements
Packing Packing type: • 1 Pair (1 left and 1 right) of gloves per inner wrapper. • 1 inner wrapper per pouch. • 50 pouches per inner (dispenser) box. • 400/ 500 pairs in an outer carton as per customer requirement.	Shall comply with standard packing and customer requirements

Weight chart

Size 6.0 (XS)	Size 6.5 (S)	Size 7.0	Size 7.5 (M)	Size 8.0	Size 8.5(L)
15.9 ± 0.6	18.4 ± 0.6	19.2 ± 0.6	20.0 ± 0.6	21.3 ± 0.6	23.0± 0.6

PERFORMANCE REQUIREMENTS AS PER ASTM 3577:2019 & EN 455-1;2000, EN 455-2:2009+A2:2013 & EN 455-3:2006

Sampling procedure: ISO 2859 Part-I
Sampling plan
i. General Inspection Level - For freedom from pinholes
ii. Special Inspection Level – For Physical Dimension and Physical Properties (Before ageing and after ageing)

Characteristic	Inspection Level	AQL
Freedom from holes	G-1	0.65
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Extractable Protein Content	N=3	NA
Powder amount	N=3	NA
Sterility	As per standard	N/A

Prepared By :
Name : Anjali Vinod
Designation : QA Manager
Signature :

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-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 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

TC-6176

TEST REPORT

Report No. : CH:TX:1142019073 **DATE : 17/07/2020**

ST MARYS RUBBERS PRIVATE LIMITED
GLOVES DIVISION, XVII-401A, THOTTAM KAVALA,, VIZHIKKATHODE
Kottayam-686158
IN
CONTACT PERSON : ANJALI VINOD

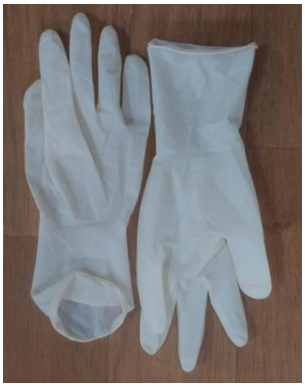
THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
STERILE LATEX SURGICAL GLOVES POWDER FREE POLYMER COATED
MANUFACTURING DATE: 2020/06
STERILISATION DATE: 2020/06
EXPIRY DATE: 2023/05

BATCH NO. 820021

BRAND MEDISMART +

PHOTO APPENDIX.



SAMPLE RECD ON 07/07/2020 **TESTING PERIOD :** 07/07/2020 - 15/07/2020

RESULT SUMMARY

TESTS	PASS	FAIL	REMARKS
EXTRACTABLE PROTEIN CONTENT			REFER RESULTS.

Per pro SGS India Private Ltd.

K. Pachaiyappan

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

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) 6608 1600 www.sgs.com
Member of the SGS Group (SGS SA)

TC-6176

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*****

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) 6608 1600 www.sgs.com
Member of the SGS Group (SGS SA)

NABL ACCREDITED
Certificate No : TC-5410

trustin
add value

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, Koovapally 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	819004	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**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 289	Passes the test
	Width (mm)		90	100	Median : 97	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	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
15/02/2019
K.SENTHILKUMAR
TECHNICAL MANAGER

Approved by
15/02/2019
M. MAHENDRAN
QUALITY MANAGER

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

1.0 STERILE LATEX SURGICAL GLOVES POWDERED (STERILE PRE-POWDERED – TYPE 1)

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.

INTDENDED USE:

- Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn on the hand of surgeon and healthcare personnel to prevent cross-contamination between healthcare personnel and patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive surgery.

GENERAL INSTRUCTIONS:

- Store the gloves in cool, dry place and away from direct sun light.
- Sterile Gloves for single use only. Sterile until package is opened or damaged.
- This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses in some individuals.
- After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.
- Reuse of gloves may cause infection, allergic reaction and poor barrier protection.
- For transient use (normally intended for continuous use for less than 60 minutes)
- Dispose after use as per hospital policies or country's regulatory norms.

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

Size	Length (mm)	Palm Width (mm)	Thickness (in mm)		
			Cuff **(Min)**	Palm **(Min)**	Finger **(Min)**
	Min	Specification			
5½	250	70 ± 6	0.10	0.10	0.10
6	265	76 ± 6			
6 ½		83 ± 6			
7	270	89 ± 6			
7 ½		95 ± 6			
8		102 ± 6			
8 ½	280	108 ± 6			
9		114 ± 6			

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.
ASTM D 3577:2019, IS 13422:1992		
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation (%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5 .5	NA
EN 455-2:2009+A2:2013		
Minimum force at break	9.0 N	9.0 N

Aqueous extractable protein content **(As per standards ASTM D 3577:2019 & EN 455-3:2006)**	< 200 μg/dm^2 – Test method ASTM D 5712-15 (2020)
Powder content (**As per standards ASTM D 3577:2019 & EN 455-3:2006)**	< 15 mg/ dm² - Test method ASTM D 6124-06 (2017)
Sterilization (for sterile product)	Ethylene Oxide
Sterility	Shall pass Sterility test as per IP /USP / EN standards
Packing Packing type: • 1 Pair of gloves per inner wrapper. • 1 inner wrapper per pouch. • 50 pouches per inner box • 500/ 400 pairs in an outer carton based on customer requirements.	Shall comply with standard packaging and customer requirements
Labeling	Shall comply with regulatory requirement and customer requirements

Weight chart

Size 6.0 (XS)	Size 6.5 (S)	Size 7.0	Size 7.5 (M)	Size 8.0	Size 8.5(L)
14.0 ± 0.6	15.8 ± 0.6	16.8 ± 0.6	18.0 ± 0.6	19.4 ± 0.6	20.8 ± 0.6

PERFORMANCE REQUIREMENTS AS PER ASTM D 3577:2019 & EN 455-1; 2000, EN 455-2:2009+A2:2013 & EN 455-3: 2006

Sampling procedure: ISO 2859 Part-I
Sampling plan : i. General Inspection Level - For freedom from pinholes
ii. Special Inspection Level – For Physical Dimension and Physical Properties (Before ageing and after ageing)

Characteristic	Inspection Level	AQL
Freedom from holes	G-1	0.65
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Extractable Protein Content	N=3	NA
Powder amount	N=3	NA
Sterility	As per standard	N/A

Approved By,

Signature :
Name : Anjali Vinod
Designation: QA Manager

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
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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-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

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

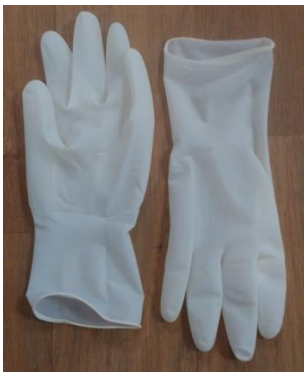
THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

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 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) 6608 1600 www.sgs.com
Member of the SGS Group (SGS SA)

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*****

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) 6608 1600 www.sgs.com
Member of the SGS Group (SGS SA)

NABL ACCREDITED
Certificate No : TC-5410

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		Results Obtained	Sample Status
			Min.	Max.		
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