

**BUREAU OF INDIAN STANDARDS**  
**MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT**  
**(MHD)**

## **AGENDA**

<b>Sectional Committee</b>	<b>Meeting No:</b>	<b>Date, Day &amp; Time</b>
Committee Meeting On Gloves (MHD 12 )	01	04 Sep 2023, 02:30pm
<b><i>Webex platform</i></b>  <b>Meeting Link:</b> <a href="https://bismanak.webex.com/bismanak/j.phpMTID=m1026623d7804995ba8a2f0fd7dcb708">https://bismanak.webex.com/bismanak/j.phpMTID=m1026623d7804995ba8a2f0fd7dcb708</a>  <b>Meeting Number:</b> 2511 485 6749  <b>Password :</b> Mhd@12		
<b>Chairperson</b>  <b>Lt Gen Sunil Kant</b>	<b>Member Secretary</b>  <b>Ms Harshada Ganesh Kadam</b>	

### **ITEM 1      PURPOSE**

1.1 During the last meeting held on 9 Aug 2023, the Committee deliberated on the comments received on IS 15354 (Part1):2018/ ISO 11193-1:2008 and decided that MTai, Mun India and Kanam latex may provide technical justification and scientific evidence regarding the proposed changes within a period of 7 days. We are yet to receive any response in the matter from Mtai and Mun India.

*The committee may kindly note.*

1.2 However, certain comments in this matter have been received from Ansell India Pvt. Ltd. and O & M Halyard Health Pvt. Ltd (copy attached)

*The committee may kindly deliberate.*

1.3 In this matter, Indian Rubber Gloves Manufacturers Association has send their representation stating that the current provisions of the standards are well in line with the Indian conditions and as such do not require any amendments (copy attached).

*The committee may kindly note and deliberate.*

1.4 Co-option request received from “Indian Rubber Glover Manufacturers Association”, dated email 31 Aug 2023 (copy attached) .

*The Committee may kindly note and deliberate.*

Date: 22.08.2023

To,  
Head (MHD)  
Room No. 459, Manakalaya Building  
Bureau of Indian Standards,  
9, Bahadur Shah Zafar Marg,  
New Delhi – 110002

**Subject: Request for consideration of updated palm thickness criteria in IS 15354 for Nitrile Examination Gloves**

Respected Sir/Madam,

We Ansell India Protective Products Pvt. Ltd, 706/7, Tower 2<sup>nd</sup>, Level 7, Seawoods Grand Central, Navi Mumbai, Maharashtra, India, hereby writing to formally submit our technical justification for the proposed update of the palm thickness criteria in IS 15354 for nitrile examination gloves. Our comprehensive analysis and research have led us to the conclusion that aligning the palm thickness criteria with the standards set by ASTM D6319 - 19 would greatly benefit the industry and ensure the quality and safety of these essential medical products.

As a reputable manufacturer and innovator in the field of medical gloves, we have meticulously reviewed the existing standards outlined in IS 15354. Through extensive research and consultation with industry experts, we have identified areas where an alignment with ASTM D6319 - 19 can enhance the accuracy and precision of palm thickness requirements. This proposed update takes into consideration the evolving demands of the medical field and ensures that nitrile examination gloves manufactured according to these revised criteria will meet the highest international quality standards.

Key points supporting our proposed update include:

**Supporting Justification #1**

Gloves with below 0.08mm palm thickness can still meet the tensile properties comfortably. This is shown in all the inspections and testing done by ADC, none has failed IS requirement for Force at Break & Elongation at Break, for both aged & un-aged glove. Our results surpassed way beyond the required criteria/limit.

Reference: Attachment 1

No.	Gloves styles & Test report no.	Palm thickness results (mm) (Min 0.08-2.00)	Before Aging		After Aging	
			Forced at Break (Min 7N)	Elongation at Break (Min 500%)	Forced at Break (Min 7N)	Elongation at Break (400%)
1	Micro-Touch N100 TAS/REP/15962	0.07	8.8	1088.2	9.8	1034.5
2	Micro-Touch Nitrile TAS/REP/15959	0.07	8.4	1074.6	9.8	1061.5
3	Micro-Flex 92-134 TAS/REP/15960	0.07	8.9	1034.4	9.4	1018.1
4	Micro-Flex 92-134 TAS/REP/15961	0.07	8.7	1064.8	9.0	1011.5
5	Micro-Touch N-100 TAS/REP/17302	0.06	10.0	1087.8	9.8	968.3
6	Microflex 92-134 TAS/REP/17303	0.07	9.8	1078.1	9.3	921.7
7	Microflex 92-134 TAS/REP/17304	0.07	9.3	1044.7	9.5	1004.8
8	Micro-Touch N100 TAS/REP/17305	0.06	9.9	1058.1	10.2	1027.8

**Supporting Justification #2**

Ansell has been commercializing globally our examination gloves, with our thickness specification of ASTM and EN. From our post-market data for the past 3 years, it was concluded no adverse event, recall, field safety notice and complaint have been issued due to thickness issue.

Brand	Volume sold in past 3 years	Adverse event reported due to palm thickness issue	Recall reported due to palm thickness issue	Field Safety Notice issued due to palm thickness issue	Complains received due to palm thickness issue
Micro-Touch Nitrile	168,486,098	Nil	Nil	Nil	NIL
Micro-Flex 92-134	506,638,870	Nil	Nil	Nil	NIL
Micro-Touch N100	4,477,000	Nil	Nil	Nil	Nil

**Supporting Justification #3**

Per the European Standard EN 455-2, there is no thickness requirement. Therefore, it is clearly being emphasized that thickness is not a crucial parameter. Rather, EU highlights it is all about the safety and performance of the glove rather than the thickness.

**Supporting Justification #4**

From the end-user point of view, glove that is thinner but with good strength means more comfortable and sensitive, with better tactility and dexterity, a preferred product especially for dental industry. Not only Ansell, but other companies in the industry also promotes thin nitrile glove.

Kindly see an example from internet as enclosed.

Reference: Attachment 2 [Thin vs. Thick Nitrile Gloves - Omni International \(omnigloves.com\)](http://omnigloves.com)

**Supporting Justification #5**

From sustainability perspective, lighter weight/thinner glove is indeed a favorable direction. By using lesser material, it reduces waste generation. Many companies explore strategies like lean manufacturing, waste reduction and product redesign to achieve material reduction goals. It is an essential aspect of sustainable practices, as it helps to conserve resources and minimize waste.

### Supporting Justification #6

Malaysia is one of the leading exporters of glove in the world. Malaysia exports to about 180 countries worldwide. Kindly refer to a report from Malaysia Rubber Council (MRC) on “Malaysia’s Exports of Rubber Gloves”, Appendix 1, Table 10: Top 20 Destination of Synthetic Rubber (SR) Gloves, Jan to Dec 2018 – 2022

Among the Top 20 countries of export, majority of the gloves are shipped to countries that refers to ASTM and EN standard, only very minimal countries (in yellow) refers ISO standard. Based on the “Value (RM Million)” and “Quantity (Million pairs)”, the mandatory ISO referenced country only amount to about 14% of the value/quantity.

Reference: Attachment 3

**Table 10: Top Twenty Destinations of SR Gloves, January to December 2018-2022**

		Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
		2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
1	USA	5,138	5,217	9,538	17,214	4,586	23,497	24,247	27,900	26,791	17,153	-73.4	-36.0	-2.8	-7.6
2	Germany	965	810	1,517	2,568	1,019	4,745	4,010	4,757	4,287	4,656	-60.3	8.6	1.4	-0.5
3	Japan	790	838	1,495	2,531	1,008	3,557	3,868	4,326	3,816	4,097	-60.2	7.4	6.3	3.6
4	United Kingdom	544	473	1,196	1,638	570	2,756	2,294	2,987	2,993	2,857	-65.2	-4.5	1.2	0.9
5	Netherlands	262	289	788	1,170	458	1,234	1,400	2,004	1,831	1,725	-60.8	-5.8	15.0	8.7
6	Australia	192	177	449	805	333	855	885	1,292	1,258	1,431	-58.6	13.7	14.8	13.7
7	Canada	277	302	792	1,151	287	1,315	1,421	2,234	1,960	1,261	-75.1	-35.6	0.9	-1.0
8	Italy	168	153	341	646	270	786	744	1,016	1,260	1,252	-58.2	-0.6	12.6	12.3
9	China	236	203	843	596	216	1,081	949	2,028	1,018	791	-63.8	-22.3	-2.2	-7.5
10	Russia	116	132	305	438	187	623	725	948	1,002	992	-57.3	-1.1	12.7	12.3
11	Turkey	111	96	163	365	178	654	596	543	827	1,103	-51.2	33.4	12.4	14.0
12	Sweden	126	133	273	427	172	576	603	740	629	704	-59.7	11.9	8.2	5.1
13	Spain	192	231	610	676	171	923	770	1,509	1,224	827	-74.8	-32.4	-2.9	-2.7
14	Belgium	120	135	284	352	158	379	426	611	436	380	-55.2	-12.9	7.1	0.01
15	France	153	123	281	413	144	684	551	712	664	558	-65.1	-15.9	-1.4	-4.9
16	Poland	160	170	418	569	136	895	982	1,324	940	702	-76.1	-25.3	-4.0	-5.9
17	South Korea	40	53	186	243	131	165	238	333	375	495	-46.0	32.1	34.9	31.6
18	Denmark	134	119	246	327	96	665	619	678	482	413	-70.8	-14.2	-8.0	-11.2
19	India	46	41	97	306	95	274	266	364	517	474	-68.9	-8.4	20.0	14.7
20	Vietnam	69	60	67	105	81	274	226	170	146	170	-22.6	16.3	4.0	-11.3

### Supporting Justification #7

We were informed that an ISO Committee Draft is being circulated on the ISO 11193-1 (NRL and Synthetic Exam) for discussion and possible revision. We understand there were feedback and proposal to revise the thickness requirement, i.e. to reduce the thickness requirement. We can see the initiative and trend is towards harmonization of ISO, EN & ASTM standards

We request your consideration of our technical justification for the proposed update to the palm thickness criteria in IS 15354. We believe that this alignment will contribute significantly to the advancement of quality standards within the industry.

Reference enclosed with this letter is a detailed technical report outlining the research, data analysis, and rationale supporting our proposal. We would greatly appreciate the opportunity to discuss this proposal further with you at your convenience. Your insights and feedback are invaluable as we work collectively to uphold the highest standards in medical glove manufacturing.

Thank you for your time and consideration. We eagerly await your response and hope for a positive outcome in the interest of enhancing healthcare safety and quality.

**Yours faithfully,**

A handwritten signature in black ink, appearing to read "Samantha Marshall". The signature is fluid and cursive, with a large initial "S" and "M".

Samantha Marshall  
Director – Regulatory Affairs EMEA & APAC HGBU



# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN add value

Sample ID No.	TAS/23-24/1414	ULR No	TC541023000000414
Sample received Date	21/04/2023	Test Report No.	TAS/REP/15962
Analysis start Date	22/04/2023	Report Date	10/05/2023
Analysis completed Date	29/04/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/44 dated 19.04.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

### SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Nitrile Examination Gloves, Imported Consignment vide B/E No. 5479545 dated 12.04.2023, Office entry No.191 MD 23 Qty:14.058 MTS From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	2302304WPM	Size	Large
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-30/23-24
Brand Name	MICRO-TOUCH N100	Mfg. Date	01/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.01.2026

### TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 247.0	Passes the test
	Width		100	120	Median : 108.0	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.12	Passes the test
	Palm (Smooth)		0.08	2.00	Median : 0.07	FAILS the test
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 8.8 Defects : 0	Passes the test
	Elongation at Break(%)		500	--	Median : 1088.2	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.8 Defects : 0	Passes the test
	Elongation at Break(%)		400	--	Median : 1034.5	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

#### Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

Remarks: Tests Carried out as per CDSCO requirements

Abbreviations: IS: Indian Standard; N: Newton; mm: Milli meter; AQL: Acceptable Quality Limit

.....End of Report.....

Authorized Signatory

K. SENTHILKUMAR  
TECHNICAL MANAGER

Authorized Signatory

M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, without written approval of the laboratory.

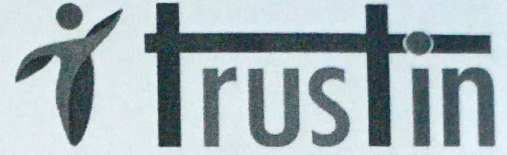
\* The test results in this report refer only to the sample tested in the laboratory and the sample submitted by the party.

NABL Accredited Laboratory vide cert. No: TC-5410 valid upto 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**  
(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)  
R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,  
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.



# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN *add value*

Sample ID No.	TAS/23-24/1411	ULR No	TC54102300000411
Sample received Date	21/04/2023	Test Report No.	TAS/REP/15959
Analysis start Date	22/04/2023	Report Date	10/05/2023
Analysis completed Date	29/04/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/41 dated 19.04.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

### SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Nitrile Powder Free, Medical Examination Gloves, Imported Consignment vide B/E No. 5462046 dated 11.04.2023, Office entry No.188 MD 23 Qty:16.592 MTS From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	2302357WPM	Size	Medium (7.5 -8.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-27/23-24
Brand Name	MICRO-TOUCH	Mfg. Date	02/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.02.2028

### TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 246.0	Passes the test
	Width		85	105	Median :95.5	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.12	Passes the test
	Palm ( Smooth)		0.08	2.00	Median : 0.07	FAILS THE TEST
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median :8.4 Defects : 0	Passes the test
	Elongation at Break(%)		500	--	Median : 1074.6	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.8 Defects : 0	Passes the test
	Elongation at Break(%)		400	--	Median : 1061.5	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

#### Opinion and interpretation (if any):

The submitted sample fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

Remarks : Tests Carried out as per CDSCO requirements

Abbreviations: IS: Indian Standard; N: Newton; mm: Milli meter; AQL: Acceptable Quality Limit

Authorized Signatory

K. SENTHILKUMAR  
TECHNICAL MANAGER



Authorized Signatory

M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

## TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,

(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)

R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,

Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.

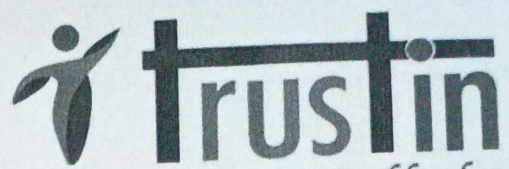
Ph: 044 22724006 Email: customers@trustinanal.com web: www.trustinanal.com







TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN add value

Sample ID No.	TAS/23-24/1412	ULR No	TC541023000000412
Sample received Date	21/04/2023	Test Report No.	TAS/REP/15960
Analysis start Date	22/04/2023	Report Date	10/05/2023
Analysis completed Date	29/04/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/42 dated 19.04.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Versatility Powder Free, Examination Gloves, Imported Consignment vide B/E No. 5475313 dated 12.04.2023, Office entry No.190 MD 23 Qty:13.437 MTS From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	23010085LC	Size	Medium (7.5-8.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-28/23-24
Brand Name	MICROFLEX	Mfg. Date	01/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.01.2026

TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status		
			Min.	Max.				
1	Dimensions (mm)	IS 15354 (Part-1) : 2018	230	--	Median : 241.0	Passes the test		
	Length				85	105	Median :98.0	Passes the test
	Width							
2	Thickness (mm)	IS 15354 (Part-1) : 2018	0.11	2.03	Median : 0.12	Passes the test		
	Finger (Textured)				0.08	2.00	Median : 0.07	FAILS the test
	Palm ( Smooth)							
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018	7.0	--	Median :8.9	Passes the test		
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01				Defects : 0			
	Elongation at Break(%)				500		--	Median : 1034.4
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018	7.0	--	Median : 9.4	Passes the test		
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01				Defects : 0			
	Elongation at Break(%)				400		--	Median : 1018.1
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test		

Opinion and interpretation (if any):  
The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

Remarks : Tests Carried out as per CDSCO requirements  
Abbreviations : IS : Indian Standard; N : Newton; mm : Milli meter; AQL: Acceptable Quality Limit  
.....End of Report.....

Authorized Signatory  
*[Signature]*  
K. SENTHILKUMAR  
TECHNICAL MANAGER



Authorized Signatory  
*[Signature]*  
M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**  
(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)  
R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,  
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.



# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN *add value*

Sample ID No.	TAS/23-24/1413	ULR No	TC54102300000413
Sample received Date	21/04/2023	Test Report No.	TAS/REP/15961
Analysis start Date	22/04/2023	Report Date	10/05/2023
Analysis completed Date	29/04/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/43 dated 19.04.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

### SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Versatility Powder Free, Examination Gloves, Imported Consignment vide B/E No. 5459927 dated 11.04.2023, Office entry No.189 MD 23 Qty:15.816 MTS From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	23010026LC	Size	Large (8.5 - 9.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-29/23-24
Brand Name	MICROFLEX	Mfg. Date	01/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.01.2026

### TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 241.0	Passes the test
	Width		100	120	Median :108.0	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.13	Passes the test
	Palm (Smooth)		0.08	2.00	Median : 0.07	FAILS the test
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median :8.7 Defects : 0	Passes the test
	Elongation at Break(%)		500	--	Median : 1064.8	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N)13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.0 Defects : 0	Passes the test
	Elongation at Break(%)		400	--	Median : 1011.5	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

#### Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

**Remarks :** Tests Carried out as per CDSCO requirements

**Abbreviations:** IS: Indian Standard; N : Newton; mm: Milli meter; AQL: Acceptable Quality Limit  
....End of Report....

Authorized Signatory

**K. SENTHILKUMAR**  
TECHNICAL MANAGER

Authorized Signatory

**M. MAHENDRAN**  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**  
(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)  
R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,  
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.





# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN add value

Sample ID No.	TAS/23-24/2813	ULR No	TC541023000001581
Sample received Date	17/07/2023	Test Report No.	TAS/REP/17302
Analysis start Date	17/07/2023	Report Date	25/07/2023
Analysis completed Date	24/07/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/257 dated 11.07.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

## SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Nitrile Powder Free, Medical Examination Gloves, Imported Consignment vide B/E No. 5462046 dated 11.04.2023, From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	2302357WPM	Size	Medium (7.5 -8.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-27/23-24
Brand Name	MICRO-TOUCH	Mfg. Date	02/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.02.2028

## TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 241.0	Passes the test
	Width		85	105	Median : 95.5	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.11	Passes the test
	Palm (Smooth)		0.08	2.00	Median : 0.06	Fails the test
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 10.0 Defects : 0	Passes the test
	Elongation at Break (%)		500	--	Median : 1087.8	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.8 Defects : 0	Passes the test
	Elongation at Break (%)		400	--	Median : 968.3	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

### Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

**Remarks :** Tests Carried out as per CDSCO requirements

**Abbreviations :** IS: Indian Standard; N : Newton; mm: Milli meter; AQL: Acceptable Quality Limit  
.....End of Report.....

Authorized Signatory

K. SENTHILKUMAR  
TECHNICAL MANAGER

Authorized Signatory

M. MAHENDRAN  
QUALITY MANAGER

- \* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**

(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)

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



# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN *add value*

Sample ID No.	TAS/23-24/2814	ULR No	TC541023000001582
Sample received Date	17/07/2023	Test Report No.	TAS/REP/17303
Analysis start Date	17/07/2023	Report Date	25/07/2023
Analysis completed Date	24/07/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/257 dated 11.07.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

## SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Versatility Powder Free, Examination Gloves, Imported Consignment vide B/E No. 5475313 dated 12.04.2023, From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	2301008SLC	Size	Medium (7.5-8.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-28/23-24
Brand Name	MICROFLEX	Mfg. Date	01/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.01.2026

## TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018	230	--	Median : 241.0	Passes the test
	Length					
	Width					
2	Thickness (mm)	IS 15354 (Part-1) : 2018	0.11	2.03	Median : 0.12	Passes the test
	Finger (Textured)					
	Palm (Smooth)					
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018	7.0	--	Median : 9.8 Defects : 0	Passes the test
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01					
	Elongation at Break(%)					
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018	7.0	--	Median : 9.3 Defects : 0	Passes the test
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01					
	Elongation at Break(%)					
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

### Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

**Remarks:** Tests Carried out as per CDSCO requirements

**Abbreviations:** IS: Indian Standard; N: Newton; mm: Milli meter; AQL: Acceptable Quality Limit

...End of Report...

Authorized Signatory

K. SENTHILKUMAR  
TECHNICAL MANAGER

Authorized Signatory

M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**  
(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)

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](mailto:customercare@trustingroup.in), web: [www.trustingroup.in](http://www.trustingroup.in)



# TEST REPORT



SAMPLE NOT DRAWN BY TRUSTIN *add value*

Sample ID No.	TAS/23-24/2815	ULR No	TC541023000001583
Sample received Date	17/07/2023	Test Report No.	TAS/REP/17304
Analysis start Date	17/07/2023	Report Date	25/07/2023
Analysis completed Date	24/07/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/257 dated 11.07.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

## SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Versatility Powder Free, Examination Gloves, Imported Consignment vide B/E No. 5459927 dated 11.04.2023, From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	23010026LC	Size	Large (8.5-9.0)
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-29/23-24
Brand Name	MICROFLEX	Mfg. Date	01/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.01.2026

## TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 241.0	Passes the test
	Width		100	120	Median : 106	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.12	Passes the test
	Palm (Smooth)		0.08	2.00	Median : 0.07	Fails the test
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.3 Defects : 0	Passes the test
	Elongation at Break(%)		500	--	Median : 1044.7	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.5 Defects : 0	Passes the test
	Elongation at Break(%)		400	--	Median : 1004.8	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

### Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

**Remarks:** Tests Carried out as per CDSCO requirements

**Abbreviations:** IS: Indian Standard; N : Newton; mm: Milli meter; AQL: Acceptable Quality Limit

....End of Report....

Authorized Signatory

K. SENTHILKUMAR  
TECHNICAL MANAGER

Authorized Signatory

M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**

(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)

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](mailto:customercare@trustingroup.in), web: [www.trustingroup.in](http://www.trustingroup.in)



## TEST REPORT

SAMPLE NOT DRAWN BY TRUSTIN *add value*

Sample ID No.	TAS/23-24/2816	ULR No	TC541023000001584
Sample received Date	17/07/2023	Test Report No.	TAS/REP/17305
Analysis start Date	17/07/2023	Report Date	25/07/2023
Analysis completed Date	24/07/2023	Report type	Original
Customer Ref No.	No. 24/Trustin/2023-24/257 dated 11.07.2023	Total Page(s)	1 of 1
Name of the customer	M/s. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION		
Address	Assistant Drugs Controller(I) CDSCO Seaport Panvel, M/s. JWR Logistic Pvt.Ltd. 15-45, National Highway 4B, Panvel-JNPT Highway, Village Padeghar, Post-Vahal, Panvel - 410206, Maharashtra.		

## SAMPLE DETAILS

Name of the sample	Examination Gloves	Test Method/ Specification	IS 15354 (Part-1) : 2018
Sample Description	Non-Sterile Nitrile Examination Gloves, Imported Consignment vide B/E No. 5479545 dated 12.04.2023, From M/s. Ansell Global Trading Center Malaysia SDN BHD, Malaysia.		
Batch No	2302304WPM	Size	Large
CHA No.	11/730	CHA	Nagarkot Forwarders Pvt.Ltd.
Quantity received	600 Pcs.	Sample No.	MD-30/23-24
Brand Name	MICRO-TOUCH N100	Mfg. Date	02/2023
Imported By	M/s. Ansell India Protective Products Pvt. Ltd., Mumbai.	Exp. Date	27.02.2028

## TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	Dimensions (mm)	IS 15354 (Part-1) : 2018				
	Length		230	--	Median : 243.0	Passes the test
	Width		100	120	Median : 109	Passes the test
2	Thickness (mm)	IS 15354 (Part-1) : 2018				
	Finger (Textured)		0.11	2.03	Median : 0.12	Passes the test
	Palm (Smooth)		0.08	2.00	Median : 0.06	Fails the test
3	Physical Properties - Before Ageing	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 9.9 Defects : 0	Passes the test
	Elongation at Break(%)		500	--	Median : 1058.1	Passes the test
4	Physical Properties - After Ageing @ 70°C for 7 days	IS 15354 (Part-1) : 2018				
	Force at Break (N) 13 Pcs @ AQL : 4.0 Accept : 01		7.0	--	Median : 10.2 Defects : 0	Passes the test
	Elongation at Break(%)		400	--	Median : 1027.8	Passes the test
5	Water Tightness Test 500 Pcs @ AQL : 2.5	IS 15354 (Part-1) : 2018	--	21 Pcs	Defects : 0	Passes the test

## Opinion and interpretation (if any):

The submitted sample Fails as per IS 15354 (Part-1) : 2018 Specifications with respect to the above tests only.

**Remarks :** Tests Carried out as per CDSCO requirements

**Abbreviations :** IS: Indian Standard; N : Newton; mm: Milli meter; AQL: Acceptable Quality Limit

...End of Report...

Authorized Signatory

*[Signature]*  
25/07/2023

K. SENTHILKUMAR  
TECHNICAL MANAGER

Authorized Signatory

*[Signature]*  
25/07/2023

M. MAHENDRAN  
QUALITY MANAGER

\* This test report shall not be reproduced except in full, 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 30/03/2024, CDSCO Registration No : TL/MD/2020/000002

**TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED,**

(An ISO 17025 : 2017 Accredited / CDSCO & BIS Approved Testing Laboratory)

R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,

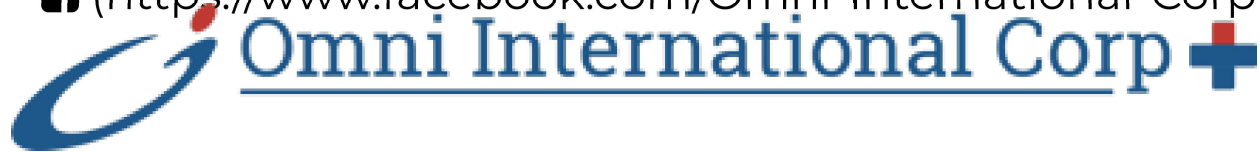
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.

Ph: 044-22731006, Email : [customercare@trustingroup.in](mailto:customercare@trustingroup.in), web: [www.trustingroup.in](http://www.trustingroup.in)

High-Quality Products for Wholesalers & Distributors

 (<https://www.linkedin.com/company/omni-international-corp/>)

 (<https://www.facebook.com/Omni-International-Corp-650995655355810>)



(<https://omnigloves.com/>)



**Address**

35 Constitution Dr. Suite 1D, Bedford, NH 03110



**Phone Number**(<https://goo.gl/maps/pXfyXyXkDLT2>)

(603) 471-1499

Search 

## Thin vs. Thick Nitrile Gloves

[Home \(Https://Omnigloves.Com/\)](https://Omnigloves.Com/) ▶ [All About Omni \(Https://Omnigloves.Com/Category/All-About-Omni/\)](https://Omnigloves.Com/Category/All-About-Omni/) ▶  
Thin Vs. Thick Nitrile Gloves



We rely on our hands daily which is why it's crucial to select the best hand protection for your specific use case. Nitrile gloves come in a variety of thicknesses and there is a common misconception that the thicker the glove, the better protection it provides. This simply isn't true.



Omni International is passionate about delivering gloves of the utmost quality and consistency, as well as educating the public about hand protection and the best gloves for your needs. Our gloves are trusted by medical professionals throughout the healthcare industry and have been used to protect patients and prevent the spread of harmful viruses and bacteria.

Join us as we look at the benefits of thin nitrile gloves and why it's not hard to see why they are the dominant glove design used in healthcare:

### **Cost-Effective**

Nitrile gloves were first introduced in the mid-1990s and since then, have become widely popular due to being latex-free and having allergy rates as low as 1%. (<https://www.westlab.com/blog/2017/08/17/nitrile-vs-latex-vs-vinyl-gloves>) These gloves were originally much more expensive than latex and vinyl gloves, however, due to their popularity, have become more reasonably priced in recent years.

Compared to thick nitrile gloves, thin nitrile gloves tend to be more economical and cost-effective as they require less material to create. They also allow for lower freight costs across the ocean compared to thick gloves. **For years, large manufacturers have been investing in new technology, chemical formulations, and production lines to help drive down costs a by making thinner gloves.** Medical personnel have taken extra precautions to prevent the spread of COVID-19, including changing their gloves and other personal protective equipment (PPE) more frequently. Thin nitrile gloves are a cost-effective solution as healthcare workers increase their glove usage.

### **Just as Durable**

As previously mentioned, people often associate thickness with quality and strength. However, when it comes to disposable nitrile gloves, that is not the case. In fact, you may be surprised to find out that it's quite the opposite. **Thin gloves are tactile and allow for the same durability as thicker nitrile which helps**

**when protecting against rips and tears.** This is especially important for use in the healthcare industry, as many of the people wearing the gloves are in direct contact with hazardous substances such as chemicals and bodily fluids.

Another advantage of thin nitrile gloves is that the material tends to tear when punctured. While this may seem like a disadvantage at first thought, it is an easy way to recognize that the glove has been compromised. Thick gloves are more likely to remain intact and the puncture could very well be overlooked. Healthcare professionals commonly use nitrile gloves when examining patients, so thinner gloves provide the same protection as thicker nitrile gloves – protecting them from harmful viruses and bacteria.

### **Comfort**

Thinner gloves tend to give healthcare workers greater sensitivity and a more comfortable feel. This allows for greater tactile perception when taking a pulse or inserting an IV. It makes them feel as though they're working with their bare hands which can often lead to better performance, as they don't feel restricted.

Healthcare workers also tend to feel more comfortable wearing thin gloves, as opposed to thick gloves, when completing intricate tasks or using delicate instruments. With a thicker nitrile glove, there is less give to it, thus creating more hand fatigue over the course of the day. This puts undue pressure on the wrist area that over time, may increase the chances of developing Carpal Tunnel. Thinner gauge allows for more freedom of movement.

Omni International offers a variety of thin nitrile gloves for you to choose from. Our gloves are developed with the latest technology in nitrile manufacturing, material, and formulation. They offer a comfortable fit while maintaining a superior level of tactile sensitivity. To view our full glove line, visit our website here. (<https://omnigloves.com/products/type/gloves/>)

### **About Omni International**

Omni International's focus is to import and market state-of-the-art products and to provide unparalleled service to our customers. We are proud to offer high-quality products designed to aid customers in the healthcare, food services, and industrial markets. To learn more about Omni International's products, click here. (<https://omnigloves.com/>)


← Prev Post

(<https://omnigloves.com/2021/02/23/cleo-stillman/>)

Next Post →

(<https://omnigloves.com/2021/05/17/2021-spring-idn-summit-recap/>)

Copyright © 2023 Omni International Corp., All Right Reserved

 (<https://www.facebook.com/Omni-International-Corp-650995655355810/>)

 (<https://www.linkedin.com/company/omni-international-corp/>)

**MALAYSIA'S EXPORTS OF RUBBER GLOVES**

Based on data submitted by the Malaysian rubber gloves exporters to MRC's Online Glove-Export Registration Exercise

**Table 1: Export of Rubber Gloves, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
Medical	15,272	14,435	30,342	46,270	18,300	74,087	71,731	87,142	85,544	75,161	-60.4	-12.1	4.6	0.4
Non-medical	2,309	2,470	3,996	4,900	2,680	7,405	7,808	8,613	6,667	6,240	-45.3	-6.4	3.8	-4.2
Total Gloves	17,581	16,905	34,338	51,170	20,980	81,492	79,539	95,755	92,211	81,401	-59.0	-11.7	4.5	-0.03

**Table 2: Rubber Gloves Export by Material Type, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
NR	6,636	5,992	12,000	14,771	9,313	30,356	28,204	32,051	33,090	33,487	-36.9	1.2	8.8	2.5
SR	10,945	10,913	22,338	36,399	11,667	51,136	51,335	63,704	59,121	47,914	-67.9	-19.0	1.6	-1.6
Total Gloves	17,581	16,905	34,338	51,170	20,980	81,492	79,539	95,755	92,211	81,401	-59.0	-11.7	4.5	-0.03
NR:SR ratio	38:62	35:65	35:65	29:71	44:56	37:63	35:65	33:67	36:64	41:59				

**Table 3: Examination Gloves Export by Material Type, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
NR	4,401	4,044	9,404	11,789	6,294	26,125	25,112	28,682	29,742	29,908	-46.6	0.6	9.4	3.4
SR	9,199	8,899	19,208	32,645	9,679	46,127	45,012	56,825	54,097	43,209	-70.4	-20.1	1.3	-1.6
Exam Gloves	13,600	12,943	28,612	44,434	15,973	72,252	70,124	85,507	83,839	73,117	-64.1	-12.8	4.1	0.3
Ratio NR:SR	32:68	31:69	33:67	27:73	39:61	36:64	36:64	34:66	35:65	41:59				

**Table 4: Surgical Gloves Export by Material Type, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
NR	1,056	923	1,272	1,371	1,774	1,506	1,369	1,465	1,500	1,826	29.4	21.7	13.8	4.9
SR	535	569	454	432	532	197	238	164	155	184	23.4	18.7	-0.1	-1.7
Surgical Gloves	1,591	1,492	1,726	1,803	2,306	1,703	1,607	1,629	1,655	2,010	28.0	21.4	9.7	4.2
Ratio NR:SR	66:34	62:38	74:26	76:24	77:23	88:12	85:15	90:10	91:9	91:9				

**Table 5: Top Twenty Destinations of Rubber Gloves, January to December 2018-2022**

		Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
		2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
1	USA	5,969	6,024	11,074	19,400	5,796	25,874	26,603	31,166	30,092	19,851	-70.1	-34.0	-0.7	-6.4
2	Japan	1,111	1,154	1,942	2,949	1,353	4,340	4,626	5,188	4,440	4,790	-54.1	7.9	5.1	2.5
3	Germany	1,279	1,046	2,281	3,203	1,351	6,311	5,104	6,096	5,537	5,613	-57.8	1.4	1.4	-2.9
4	China	561	543	1,618	1,543	1,281	2,818	2,893	4,771	3,532	5,383	-17.0	52.4	22.9	17.6
5	United Kingdom	729	651	1,969	2,282	734	3,356	2,919	4,515	4,057	3,130	-67.8	-22.8	0.2	-1.7
6	Italy	436	398	766	1,132	622	2,002	1,913	2,213	2,238	2,475	-45.1	10.6	9.3	5.4
7	Turkey	379	366	743	1,195	593	2,351	2,416	2,716	3,640	3,229	-50.4	-11.3	11.8	8.3
8	Netherlands	322	381	1,030	1,440	583	1,435	1,709	2,478	2,294	2,103	-59.5	-8.3	16.1	10.0
9	Brazil	491	477	872	1,276	583	2,825	3,045	3,578	3,604	3,465	-54.3	-3.9	4.4	5.2
10	Australia	307	274	732	1,006	564	1,214	1,213	1,776	1,620	2,251	-43.8	38.9	16.5	16.7
11	Hong Kong	497	296	266	290	522	2,850	1,686	991	665	2,127	80.0	220.0	1.2	-7.0
12	Russia	250	287	535	718	424	1,181	1,373	1,482	1,630	1,795	-41.0	10.2	14.1	11.0
13	France	401	311	760	797	380	1,474	1,230	1,623	1,246	1,204	-52.3	-3.4	-1.4	-4.9
14	Spain	379	397	1,179	1,110	369	1,802	1,642	2,803	2,022	1,622	-66.8	-19.7	-0.7	-2.6
15	India	210	210	487	870	360	1,246	1,264	1,685	2,245	1,894	-58.6	-15.6	14.5	11.0
16	Canada	323	364	1,033	1,585	360	1,459	1,664	2,747	2,733	1,379	-77.3	-49.5	2.8	-1.4
17	South Korea	158	160	414	542	351	601	658	836	933	1,080	-35.2	15.7	22.2	15.8
18	Belgium	278	274	444	497	296	587	602	848	608	514	-40.6	-15.4	1.5	-3.3
19	Argentina	104	112	202	404	286	558	652	682	1,158	1,369	-29.2	18.3	28.6	25.2
20	Saudi Arabia	97	100	149	335	226	472	512	566	854	892	-32.5	4.4	23.6	17.2

**Table 6: Rubber Glove Export by Type of Use, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
Examination	13,600	12,943	28,612	44,434	15,973	72,252	70,124	85,507	83,839	73,117	-64.1	-12.8	4.1	0.3
Surgical	1,591	1,492	1,726	1,803	2,306	1,703	1,607	1,629	1,655	2,010	28.0	21.4	9.7	4.2
High Risk	81	0.15	4.34	33	20	132	0.32	6	50	34	-37.9	-29.3	-28.9	-28.2
Industrial	1,343	1,504	2,698	3,051	1,443	5,407	6,078	6,719	4,584	4,604	-52.7	0.4	1.8	-3.9
Clean Room	348	356	501	853	619	844	715	827	951	748	-27.4	-21.4	15.5	-3.0
Household	501	464	524	518	476	551	354	360	369	308	-8.0	-16.6	-1.2	-13.5
Food Handling	111	125	239	424	121	596	621	651	715	550	-71.4	-23.0	2.3	-2.0
Others	6	21	34	54	21	7	40	56	48	30	-63.5	-36.1	30.9	42.9
Total	17,581	16,905	34,338	51,170	20,980	81,492	79,539	95,755	92,211	81,401	-59.0	-11.7	4.5	-0.03

**Table 7: Examination Glove Exports by Powdered and Powder-free Types, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
Powdered	2,050	1,715	3,422	5,131	2,193	13,674	12,448	14,073	14,998	12,967	-57.3	-13.5	1.7	-1.3
Powder-Free	11,550	11,228	25,190	39,303	13,780	58,578	57,676	71,434	68,841	60,150	-64.9	-12.6	4.5	0.7
Exam Gloves	13,600	12,943	28,612	44,434	15,973	72,252	70,124	85,507	83,839	73,117	-64.1	-12.8	4.1	0.3
Ratio P/PF	15:85	13:87	12:88	12:88	14:86	19:81	18:82	16:84	18:82	18:82				

**Table 8: Surgical Glove Exports by Powdered and Powder-free Types, January to December 2018-2022**

	Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
	2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
Powdered	328	238	268	326	329	734	622	485	522	453	1.0	-13.2	0.03	-11.4
Powder-Free	1,263	1,254	1,458	1,477	1,978	969	985	1,144	1,133	1,557	33.9	37.4	11.9	12.6
Surgical Gloves	1,591	1,492	1,726	1,803	2,307	1,703	1,607	1,629	1,655	2,010	28.0	21.4	9.7	4.2
Ratio P/PF	21:79	16:84	16:84	18:82	14:86	43:57	39:61	30:70	32:68	23:77				

**Table 9: Top Twenty Destinations of NR Gloves, January to December 2018-2022**

		Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
		2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
1	USA	831	807	1,536	2,186	1,210	2,377	2,356	3,266	3,301	2,698	-44.6	-18.3	9.9	3.2
2	China	325	340	775	947	1,065	1,737	1,944	2,743	2,514	4,592	12.4	82.6	34.5	27.5
3	Brazil	418	382	669	959	508	2,429	2,515	2,858	2,960	3,007	-47.0	1.6	5.0	5.5
4	Hong Kong	433	238	183	163	481	2,547	1,410	697	463	1,950	194.5	320.9	2.7	-6.5
5	Turkey	268	270	580	830	415	1,697	1,820	2,173	2,813	2,126	-50.0	-24.4	11.5	5.8
6	Italy	268	245	425	486	352	1,216	1,169	1,197	978	1,223	-27.6	25.0	7.0	0.1
7	Japan	321	316	447	418	345	783	758	862	624	693	-17.5	11.0	1.8	-3.0
8	Germany	314	236	764	635	332	1,566	1,094	1,339	1,250	957	-47.7	-23.5	1.4	-11.6
9	India	164	169	390	564	265	972	998	1,321	1,728	1,420	-53.0	-17.8	12.8	9.9
10	Russia	135	156	230	281	237	558	648	533	627	804	-15.5	28.1	15.2	9.6
11	France	249	188	479	383	236	790	678	911	583	646	-38.5	10.8	-1.3	-4.9
12	Australia	115	97	283	201	231	359	328	484	362	820	15.1	126.3	19.1	22.9
13	South Korea	118	107	228	299	220	436	420	503	558	585	-26.5	4.8	16.9	7.7
14	Argentina	84	88	139	296	210	461	534	509	936	995	-29.0	6.3	25.6	21.2
15	Spain	187	166	569	434	198	879	872	1,294	798	795	-54.4	-0.3	1.3	-2.5
16	Saudi Arabia	70	78	115	288	186	338	411	448	754	745	-35.5	-1.2	27.5	21.9
17	United Kingdom	185	178	773	644	164	600	625	1,528	1,064	273	-74.6	-74.3	-2.9	-17.8
18	Belgium	158	139	160	145	138	208	176	237	172	134	-5.2	-21.8	-3.4	-10.4
19	Egypt	96	69	107	219	136	640	454	467	606	559	-37.9	-7.7	9.2	-3.3
20	Netherlands	60	92	242	270	125	201	309	474	463	378	-53.7	-18.3	20.3	17.1

**Table 10: Top Twenty Destinations of SR Gloves, January to December 2018-2022**

		Value (RM million)					Quantity (Million pairs)					% Change (22/21)		CAGR (2018-2022)	
		2018	2019	2020	2021	2022	2018	2019	2020	2021	2022	Value	Qty	Value	Qty
1	USA	5,138	5,217	9,538	17,214	4,586	23,497	24,247	27,900	26,791	17,153	-73.4	-36.0	-2.8	-7.6
2	Germany	965	810	1,517	2,568	1,019	4,745	4,010	4,757	4,287	4,656	-60.3	8.6	1.4	-0.5
3	Japan	790	838	1,495	2,531	1,008	3,557	3,868	4,326	3,816	4,097	-60.2	7.4	6.3	3.6
4	United Kingdom	544	473	1,196	1,638	570	2,756	2,294	2,987	2,993	2,857	-65.2	-4.5	1.2	0.9
5	Netherlands	262	289	788	1,170	458	1,234	1,400	2,004	1,831	1,725	-60.8	-5.8	15.0	8.7
6	Australia	192	177	449	805	333	855	885	1,292	1,258	1,431	-58.6	13.7	14.8	13.7
7	Canada	277	302	792	1,151	287	1,315	1,421	2,234	1,960	1,261	-75.1	-35.6	0.9	-1.0
8	Italy	168	153	341	646	270	786	744	1,016	1,260	1,252	-58.2	-0.6	12.6	12.3
9	China	236	203	843	596	216	1,081	949	2,028	1,018	791	-63.8	-22.3	-2.2	-7.5
10	Russia	116	132	305	438	187	623	725	948	1,002	992	-57.3	-1.1	12.7	12.3
11	Turkey	111	96	163	365	178	654	596	543	827	1,103	-51.2	33.4	12.4	14.0
12	Sweden	126	133	273	427	172	576	603	740	629	704	-59.7	11.9	8.2	5.1
13	Spain	192	231	610	676	171	923	770	1,509	1,224	827	-74.8	-32.4	-2.9	-2.7
14	Belgium	120	135	284	352	158	379	426	611	436	380	-55.2	-12.9	7.1	0.01
15	France	153	123	281	413	144	684	551	712	664	558	-65.1	-15.9	-1.4	-4.9
16	Poland	160	170	418	569	136	895	982	1,324	940	702	-76.1	-25.3	-4.0	-5.9
17	South Korea	40	53	186	243	131	165	238	333	375	495	-46.0	32.1	34.9	31.6
18	Denmark	134	119	246	327	96	665	619	678	482	413	-70.8	-14.2	-8.0	-11.2
19	India	46	41	97	306	95	274	266	364	517	474	-68.9	-8.4	20.0	14.7
20	Vietnam	69	60	67	105	81	274	226	170	146	170	-22.6	16.3	4.0	-11.3

To  
Medical Equipment & Hospital Planning Dept.  
Bureau of Indian Standards, New Delhi

**Company: O&M Halyard Health India Pvt. Ltd**

**Proposal: Amendment of *the current standard IS 15354 15354 (Part 1):2018 standard for Medical Examination gloves***

**Background:**

Examination gloves are an integral part of Personal Protection (PPE) for healthcare professionals and important part of an infection-control strategy.

Examination gloves are so versatile that they're widely used in medical and healthcare fields, and more. They are composed of different materials like latex, nitrile, poly vinyl chloride etc. with unique properties and advantages. There is increasing need for thinner but strong gloves based on the tactile sensitivity required during the examination procedure.

The current **IS 15354 (Part 1):2018** provides standard for Single use Medical examination gloves. However, the specification for thickness is high and hence the users will only get the thicker range of gloves. Hence, we propose amendment of the IS 15354 in reference with other international standards like ASTM in terms of separate specifications for latex and nitrile, lower thickness and other associated parameters.

**Any specific problem being faced this standard:**

- 1) Limited options for users: The current specification minimum thickness of 0.08mm and this limits the options for users.
- 2) Impact on effectiveness: The end user will have impact on the tactile sensitivity as they will only get thicker gloves even if the procedure may require lower thickness.
- 3) Cost burden: The higher thickness of gloves increases the cost of the gloves. The users and ultimately patient will continue to bear higher cost of gloves.

**Who will benefit from this standard:**

- 1) Healthcare professionals involved in various examination gloves
- 2) Consumers
- 3) GeM Portal buyers
- 4) Hospital procurement team in procuring gloves meeting the IS standards
- 5) Glove Manufacturers and Importers



## Amendments proposed for Current IS 15354 Standard:

- 1) Separate specifications for Latex Rubber and Nitrile gloves
- 2) Reduction in thickness from 0.08mm to 0.05 mm for Nitrile gloves
- 3) Change in Force at break parameter to Tensile strength

We propose the following changes as in below tables:

### 1) Rubber Exam Gloves: IS 15354 Type 1

Sr. No.	Test Specifications	IS 15354 (Part 1):2018 Type 1 Gloves (Rubber Exam) Standards		ASTM D 3578-19 Rubber Examination Gloves Standards	
1	Minimum Thickness Finger and Palm	Finger and Palm	Smooth: 0.08 mm Fingered: 0.11 mm	Finger and Palm	0.08 mm
2	Physical Properties- Before Ageing	Force at Break (N)	7 N	Tensile Strength (Mpa)	18/14 MPa Min
		Elongation at Break (%)	650%	Elongation at Break (%)	650%
3	Physical Properties- After Accelerated Ageing	Force at Break (N)	6 N	Tensile Strength (Mpa)	14 MPa Min
		Elongation at Break (%)	500%	Elongation at Break (%)	500%
4	Water Tightness Test	AQL	2.5	AQL	2.5

### 2) Nitrile Exam Gloves): IS 15354 (Part 1):2018 Nitrile Exam GLoVES Standards

Sr. No.	Test Specifications	IS 15354 (Part 1):2018 Type 2 Gloves (Nitrile Exam) Standards		ASTM D6319-19 Nitrile Exam Gloves Standards	
1	Minimum Thickness Finger and Palm	Finger and Palm	Smooth: 0.08 mm Fingered: 0.11 mm	Finger and Palm	0.05 mm
2	Physical Properties- Before Ageing	Force at Break (N)	7 N	Tensile Strength (Mpa)	14 MPa Min
		Elongation at Break (%)	500%	Elongation at Break (%)	500%
3	Physical Properties- After Accelerated Ageing	Force at Break (N)	7 N	Tensile Strength (Mpa)	14 MPa Min
		Elongation at	400%	Elongation at Break (%)	400%

		Break (%)			
4	Water Tightness Test	AQL	2.5	AQL	2.5

**Scientific Evidence:**

**International Standard for Rubber Examination Gloves**

**ASTM D 3578-19 : Standard Practice for Rubber—Measurement of Dimensions**

*This specification covers certain requirements for natural rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures. It also covers natural rubber gloves used in handling contaminated medical material*

**International Standard for Nitrile Examination Gloves:**

**ASTM D6319 – 19: Standard Specification for Nitrile Examination Gloves for Medical Application**

*This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.*



# Indian Rubber Glove Manufacturers Association,

C-171, Defence Colony, Ground Floor, New Delhi-110024

Date 14<sup>th</sup> August 2023

To

The Director General  
Bureau of Indian Standards  
9, B.S. Zafar Marg  
New Delhi-110002

**Subject : The Technical Committee MDH 12, Likely to be influenced to modify BIS Standards on Gloves to promote Imported Spurious Repacked Gloves marked with BIS, Mark and being sold to Hospitals/ Medical Staff**

Respected Sir,

We are sending the confidential information, with respect to the manufacturers, involved in import of spurious loose packed gloves, without any certification and now intend to legalise the same by suggesting BIS to amend its standards on Gloves.

While they continue misusing the ISI mark by using ISI MARK CERTIFICATION on its PACKAGING, even when they have no ISI mark/ certificate, they are importing spurious gloves ( in loose and in gunny bags ) and repacking the same and marking and selling – cheating and defrauding the Hospital Procurements. The above activity is a clear contravention of Sectio 11(1), of the Bureau of Indian Standards Act, 2016. The gloves are marked in violation of BIS Rules, and it need an immediate action to stop and penalise such industries.

**The delegation of such dubious manufacturers from countries like Malaysia, Thailand ie Ansell, Halyard, Hertlega, have successfully met on 09.08.2023, with MHD 12 (under MHD Dept of BIS )- Not Desired and Uncalled for :**

- a) Mr Amit Rai
- b) Mr Bhushan Dhoot
- c) Mr Saurabh Sharma
- d) Mr Unnikrishanan, BIS
- e) Ms Harshada, BIS

**During the above discussions with MHD 12 Officials of BIS, such importers have been making an attempt to influence the committee members on**

Consideration of ASTM Standards for single use medical examination gloves

They have suggested to modify the existing standard, to reduce the thickness of gloves, without caring for its use for Indian Environment

They want to be a permanent member of MHD 12, to settle their own objective

They want to impose their intention of diluting the existing standards saying that ASTM Standards are better, and acceptability of ISO 11193 (without any data)

They want to influence MDH 12, saying that BIS Standard IS 15354 is difficult, instead BIS is already certified 10 companies for IS 15354.

The fact of the case is as under:

1. Bureau of Indian Standards has published an Indian Standard, IS 15354 (Pat-1) :2018 – Single -Use Medical Examination Gloves, Part 1 Specification for Gloves Made from Rubber

Latex or Rubber Solution, and Type 2, Gloves, made primarily from nitrile rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic-elastomer solution. There are already many BIS certified companies manufacturing the gloves, and these companies are capable of supplying the quality product to the Hospital Staff. We may bring to your kind notice that CDSCO, rule Gazette is mandated to be implemented w e from 1<sup>st</sup> October 2022, but it is noted that Health and Safety aspects of patients, is needing your Intervention because all medical device manufacturers are now required to complete the mandatory registration for class A and class B medical devices. This includes Gloves, as a matter of concerns. BIS Compliance for Rule 7 of Chapter 2, of MDR 2017, is necessary. This will facilitate the BIS Licences, to make effective use of License issued by BIS. In addition , the list certified by CDSCO, for 28 number of labs, is not indicating any laboratory already certified by BIS for testing of gloves, instead of the facts, that BIS has approved list of laboratories for Testing of Gloves. **The nitrile gloves, being imported from Malaysia, having spurious quality , are totally ignoring the Make in India Concept.** The necessary efforts have been made by our group , to make the Make in India, PM success by creating our own in house manufacturing facility in India. The use of Nitrile Gloves in Govt Hospitals ( AIIMS and State Run Govt Hospitals ), they have been procuring the medical devices through GEM/ E Procurement – However while deciding the specifications required, the main clause for their conformity to relevant standard is excluded. As a result substandard and spurious quality of medical gloves are getting their entry for the most significant activity of the Hospitals. All the medical staff including surgeons and nurses, in leading hospitals are facing the dilemma in Operation Theatres, especially when they are dealing with critical cases such as delivery by a pregnant HIV positive woman or surgery on a patient suffering from blood-borne infections. The surgical gloves procured in bulk from manufacturing units are so inferior that one needs to change two or three pairs during one operation. These gloves keep tearing, putting doctors and nurses at the risk of contracting blood-borne infections from patients suffering from HIV, Hepatitis B Virus. Mandatory QCO, in this respect, for use of only ISI Mark use of Nitrile Gloves, should be considered.

Therefore, BIS should immediately consider that the lives of thousands of patients and doctors is not compromised every day. The poor quality of surgical gloves in hospitals, need a check which is possible through compliance to CDSCO Gazette Notification. (Rule 7 of Chapter 2) , **and without allowing any tempering of existing Standards through MHD 12.**

BIS, may consider to:

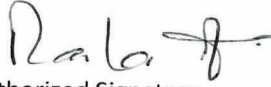
1. An immediate stop, to counter the influence of such importers attempt in amending the existing standards
2. To direct CDSCO, to implement Rule 2 of chapter 7, ( it will facilitate BIS Licenses to sell their products to ensure the safety and health concerns , mainly for Gloves manufacturers )
3. To direct CDSCO, to update their list of certified labs, which need to include the BIS RECOGNISED Labs for Gloves.

The above, actions on part of BIS, will ensure compliance to BIS Act/ CDSCO, NOTIFICATION, in an effective way.

Thanking you

Yours faithfully

For Indian Rubber Gloves manufacturers Association

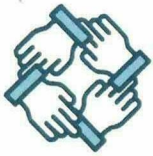


Authorized Signatory

Copy To :

DDGT, HCMD ( Shri Unnikrishanan, )

✓ H ( MHD ), Ms Harshada



# Indian Rubber Glove Manufacturers Association,

C-171, Defence Colony, Ground Floor, New Delhi-110024

Date: 18<sup>th</sup> August 2023

To

The Director General  
Bureau of Indian Standards  
9, B.S. Zafar Marg  
New Delhi-110002

Subject : **Safety & Health of Consumers Ignored by the BIS Technical Committee (MDH 12 ), while taking up the Unwanted Review of Standards on Gloves – under the Influence of Importers.**

Respected Sir,

We, the Indian Gloves Manufacturers association wish to bring to your kind notice the following facts:

Under Medical Devices Rules, 2017, a Notification was issued with effect from 1<sup>st</sup> October, 2022 that Examination Gloves (both nitrile & Latex) shall mandatorily meet the requirements of **IS 13422 & 15354 (Part-1, Part-2): 2018**. We are concerned over the blatant violation of IS standards mentioned above by importers. It is submitted that till now, 50 containers of spurious, imported gloves imported by Importers was sent by Customs Department to quality labs and that they have failed the BIS standards. It has been observed now that these importers are importing gloves in LOOSE and BULK through different HSN codes and are repacking them as Medical Examination Gloves thus bypassing the observance of IS standards. We understand that Importers are importing those gloves which are rejected by Buyers of developed countries. For the last 12 months, 4.2 billion numbers of gloves valuing US \$ 244 million (about Rs 2000 crores) were imported in bulk by the importers.

IRGMA is seriously concerned over the above scenario and it should be a national concern, because unsafe gloves are used in health sector. All the medical staff including surgeons and nurses are exposed to health risks especially when they are dealing with critical cases such as delivery by a pregnant HIV positive woman or surgery on a patient suffering from blood-borne infections. Some gloves are so inferior that one needs to change two or three pairs during one operation.

By setting up of manufacturing facilities in India, not only quality gloves are made available but the economy of the country is benefitted due to saving of foreign exchange (and earning of foreign exchange with exports happening in due time) but also by generation of employment.

Under the influence of Importers of Gloves, the officials of BIS have initiated an unwanted review of Standards on Gloves. We understand that importers have had a meeting with BIS officials on 09.08.2023 wherein it was decided to review the standards on gloves and data on the matter was sought. This act of undertaking the unwanted review of existing standards of BIS is highly objectionable and uncalled for.

During the above discussions with MHD 12 Officials of BIS, such importers have been making an attempt to influence the committee members on

- Consideration of ASTM Standards for single use medical examination gloves
- They have suggested to modify the existing standard, to reduce the thickness of gloves, without caring for its use for Indian Environment
- They want to be a permanent member of MHD 12, to settle their own objective
- They want to dilute the existing standards saying that ASTM Standards are better, and want that ISO 11193 (without any data) be accepted
- They want to influence MDH 12, saying that BIS Standard IS 15354 is difficult

The fact of the case is as under:

1. Bureau of Indian Standards has published an Indian Standard, IS 15354 (Part-1 & Part 2) :2018 – Single -Use Medical Examination Gloves,
2. There are upto forty BIS certified companies manufacturing the gloves, and these companies are capable of supplying the quality product to the Hospital Staff. The total investment in these manufacturing facilities is around US \$ 50 million (about Rs 450 crores) and 40,000 workers are dependent upon them for their livelihood. The leading manufacturers from India – Sri P Naveen Reddy (Navco), P R Dhaamodharam (LATRILE), Benedict Bobby Sebastian (LMS), Manmohan Singh Gulati (Tegamen) , Shaaz Mehmood (Wadi Surgical) and Vikash Anand (Kooove IOT) met BIS officials on August 16, 2023 to protest the unwanted review of BIS standards.
3. Buyers of Nitrile Gloves in Govt Hospitals who have been procuring the medical devices through GEM/ E Procurement – are failing to mention the relevant BIS standard. As a result substandard and spurious quality of medical gloves are getting their entry for the most significant activity of the Hospitals.

We may request your kind intervention for considering and issuing directives for:

1. The relevant technical committee of BIS ie MHD 12, should not be misguided by the lobby of Importers. The current provisions of standards on Gloves, are well in line with Indian Conditions and as such do not require any amendments.
2. BIS officials should consider that while formulating the current standards published years before, had carefully considered the Indian requirements and purposely chose to follow close to EU norms (EN 455) rather than relaxed US norms (ASTM D 6319) and the same was approved by the relevant technical committee keeping in view of the Indian requirements. Now, when CDSCO is trying to initiate compliance to these norms, Importers along with manufacturers of surgical gloves, who do not make any single examination gloves either in latex or nitrile are influencing BIS officials to change the norms against “Make in India” policy of Government.

Thanking you  
Yours faithfully

Indian Rubber Gloves Manufacturers Association



Authorized Signatory

Copy to:

- The Hon'ble Minister of State for Consumer affairs, food & Public Distribution  
Ministry of Consumer Affairs, Food & Public Distribution, Krishi bhawan  
New Delhi-110001





# Indian Rubber Gloves Manufacturers Association

C 171, Defence Colony, New Delhi - 110024

PAN : AAGCI9270D

TAN : DELI17522B

CIN No. : U91990DL2022NPL407216

31<sup>st</sup> August 2023

To

**The Director General  
Bureau of Indian Standards  
9, Bhahadurshah Zafar Marg  
New Delhi- 110002**

**Subject: Request for Membership in BIS Technical Committee ( MDH 12 ), for Review of Standards on Gloves**

**Respected Sir,**

We, the Indian Gloves Manufacturers association express our sincere thanks and gratitude for allowing us to meet us on 18.08.2023 and as an outcome of the meeting for your valuable guidance and suggestion to INCLUDE our expert members, in the BIS technical committee - MHD 12, to enable us to provide necessary inputs in detail ( as explained in our letter dt 18.08.2023, handed over to H (MHD) :

We would be able to represent and in consultations with the local manufacturers of the gloves, submit our inputs for review of Standards on Gloves.

The technical committee of BIS, ie MDH 12, is having participation from the learned expert members and inputs from members from the Industry Experts Groups, for relevant provisions of the standard, will be very useful.

In view of above may we request for considering :

Our request for membership of in the technical committee of BIS ie MHD 12, so that review of the existing provisions of standards on Gloves, may be taken up in view of the fact that these are well in line with Indian Conditions and as such do not require any amendments, because many BIS Licenses are already operative and all these BIS Licensee have already capacity and big investments in their plants.

We again thank you for your valuable time to present our case in this regard, and suggestion with our request for **member of the Technical Committee MHD 12.**

Thanks, and Regards.

Manmohan Singh Gulati

General Secretary, IGMA



Copy to:

For kind consideration of

1. Sc F & Head ( MHD ), MHDP, Bureau of Indian Standards  
9, Bahadurshah Zafar Marg  
New Delhi -11002
- ✓2. Ms Harshada,  
Member Secretary, ( MHD 12 )  
MHD  
Bureau of Indian Standards  
9, Bahadurshah Zafar Marg  
New Delhi -11002

