

F/UM_QD_11_18.REV 2

Quality Department

CERTIFICAT OF ANALYSIS

Nan	Name of Product : Examination Gloves						
	Parameters Limits Observations						
[A]	[A] PHYSICAL INSPECTION						
1.	Water tightness test for detection of holes	Shall not leak when tested in accordance with clause 5 of EN 455-1	No Leakage				
2.	Dimensions	Shall Comply as per Table 1 & 2 of BS EN 455-2	Comply				
3.	Tensile Strength (MPa) - Before aging - After Aging	≥ 24 MPa ≥ 12 MPa	26 MPa 13 MPa				
4.	Elongation at break - Before aging - After Aging	Min 750 % Min 560 %	770 % 570 %				
5.	Force at break - Before aging - After Aging	≥ 12 N ≥ 9 N	25 N 22 N				

The above batch complies / does not comply as per ISO EN 455-1,2,3,4 /In-House Specifications.

Tested By
Remon Zaher

QUALITY MANAGER

Asheer Danial

Certificate of Analysis

ISSUE/REV: - 1/0 Page 1 of 1 **Examination Gloves**





TEST REPORT





Sample ID No.	TAS/20-21/3046	ULR No	TC541021000000472F		
Sample received Date	20/02/2021	0/02/2021 Test Report No.			
Analysis start Daté	20/02/2021	Report Date	10/03/2021		
Analysis completed Date	09/03/2021	Report type	Original		
Customer Ref No.	Your TRF dated 23/02/2021	Total Page(s)	1 of 1		
Name of the customer	M/s. ULTRA FOR MEDICAL PRODU	M/s. ULTRA FOR MEDICAL PRODUCTS Co. (ULTRAMED)			
Address	64, Nakhla Elmotaiy St., Triumph Sq., Cairo, Egypt.	64, Nakhla Elmotaiy St., Triumph Sq., Cairo, Egypt.			

SAMPLE DETAILS					
Name of the sample	Surgical Gloves, Powder Free		EN 455-1:2000, EN 455-2& 3:2015/ISO 21171:2006		
Batch No	21A02E	Size	7.5		
Quantity received	60 Pairs	Mfg. Date	02/2021		
Brand	ULTRA SURGICAL GLOVES Exp. Date 01/2026		01/2026		
Mfg. by	M/s. ULTRA FOR MEDICAL PRODUCTS Co. (ULTRAMED), Egypt.				

		T	EST RESUL	TS		,,
S. No.	Name of the Test	Test Method/	Specification Limits		Results Obtained	Sample Status
	parameter(s)	Clause No.	Min.	Max.	Obtained	
1	Dimension					
	Length (mm)	EN 455-2:2015	270	4-	Median : 285	Passes the test
	Width (mm)	(Clause 4.2 & 4.3)	90	100	Median : 94	Passes the test
2	Physical Properties					
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0		Median : 13.4	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0	240	Median: 11.3	Passes the test
3	Freedom from Holes	EN 455-1:2000			No Holes found	Passes the test
4	Powder content (mg/glove)	EN 455-3 :2015	8	2.0	Average: 0.6	Passes the test
5	Sterility test	EP 10.0, Section 2.6.1		lence of al growth	No growth	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455- 1:2000, EN 455-2 & 3:2015 and EP 10.0 specifications with respect to the above tests only.

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

....End of Report....

K. SENTHILKUMAR
TECHNICAL MANAGER

M V TAMIL VANNAN

DY. MANAGER - MICROBIOLOGY

Approved by

10

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 30/03/2021









Sample ID No.	TAS/20-21/3047	ULR No	TC541021000000473F		
Sample received Date	pple received Date 20/02/2021 Test Report No		TAS/REP/3195		
Analysis start Date	20/02/2021	Report Date	10/03/2021		
Analysis completed Date	09/03/2021	Report type	Original		
Customer Ref No.	Your TRF dated 23/02/2021	Total Page(s)	1 of 1		
Name of the customer	M/s. ULTRA FOR MEDICAL PRODU	CTS Co. (ULTRAMED)	•		
Address	64, Nakhla Elmotaiy St., Triumph Sq.,				
Cairo, Egypt.					
	CAMBLE DETAILS				

SAMPLE DETAILS						
Name of the sample		EN 455-1:2000, EN 455-2& 3:2015/ISO 21171:2006				
Batch No	21A02E	Size	8.0			
Quantity received	60 Pairs Mfg. Date		02/2021			
Brand	Exp. Date	01/2026				
Mfg. by M/s. ULTRA FOR MEDICAL PRODUCTS Co. (ULTRAMED), Egypt.						

		Т	EST RESUL	TS	100	
S. No.	Name of the Test	Test Method/	Specification Limits		Results	Sample Status
	parameter(s)	Clause No.	Min.	Max.	Obtained	
1	Dimension					
	Length (mm)	EN 455-2:2015	270		Median : 289	Passes the test
	Width (mm)	(Clause 4.2 & 4.3)	96	108	Median : 103	Passes the test
2	Physical Properties					
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0		Median : 13.2	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0	/ W.W.	Median : 11.3	Passes the test
3	Freedom from Holes	EN 455-1:2000	12.TA	1.77	No Holes found	Passes the test
4	Powder content (mg/glove)	EN 455-3 :2015	- E	2.0	Average: 0.93	Passes the test
5	Sterility test	EP 10.0, Section 2.6.1		lence of al growth	No growth	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455- 1:2000, EN 455-2 & 3:2015 and EP 10.0 specifications with respect to the above tests only.

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

....End of Report....

Reported by

K. SENTHILKUMAR

TECHNICAL MANAGER

Reported by

M V TAMIL VANNAN
DY. MANAGER - MICROBIOLOGY

CHENNAI-44 M. MAHENDRAN
OUALITY 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 30/03/2021

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









Sample ID No.	TAS/20-21/3045	ULR No	TC541021000000471F			
Sample received Date	20/02/2021	Test Report No.	TAS/REP/3193			
Analysis start Daté	20/02/2021	Report Date	10/03/2021			
Analysis completed Date	09/03/2021	Report type	Original			
Customer Ref No.	Your TRF dated 23/02/2021	Your TRF dated 23/02/2021 Total Page(s)				
Name of the customer	M/s. ULTRA FOR MEDICAL PRODU	CTS Co. (ULTRAMED)	1)			
Address 64, Nakhla Elmotaiy St., Triumph Sq., Cairo, Egypt.						
SAMPLE DETAILS						

SAMPLE DETAILS						
Name of the sample		EN 455-1:2000, EN 455-2& 3:2015/ISO 21171:2006				
Batch No	21A01E	Size	7.0			
Quantity received	60 Pairs	Mfg. Date	01/2021			
Brand	Exp. Date	12/2025				
Mfg. by M/s. ULTRA FOR MEDICAL PRODUCTS Co. (ULTRAMED), Egypt.			pt.			

TEST RESULTS						
S. No.	Name of the Test parameter(s)	Test Method/ Clause No.	Specification Limits		Results Obtained	Sample Status
	pai ameter (3)	Clause No.	Min.	Max.	Obtained	
1	Dimension					
	Length (mm)	EN 455-2:2015	270		Median : 289	Passes the test
	Width (mm)	(Clause 4.2 & 4.3)	79	94	Median : 90	Passes the test
2	Physical Properties					
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0	***	Median : 14.2	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0		Median : 12.5	Passes the test
3	Freedom from Holes	EN 455-1:2000			No Holes found	Passes the test
4	Powder content (mg/glove)	EN 455-3 :2015	65 9 44 6	2.0	Average: 1.4	Passes the test
5	Sterility test	EP 10.0, Section 2.6.1		lence of al growth	No growth	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455-1:2000, EN 455-2 & 3:2015 and EP 10.0 specifications with respect to the above tests only.

 $\underline{Abbreviations} : EN: European \ Standard; \ mm: \ milli \ meter; \ mg: milli \ gram; \ N: \ Newton; \ mg: milli \ gram; \ N: \ Newton; \ mg: milli \ gram; \ N: \ Newton; \ mg: milli \ gram; \ N: \ Newton; \ mg: \ milli \ gram; \ n: \ Newton; \ mg: \ milli \ gram; \ n: \ Newton; \ mg: \ m$

....End of Report....

Anth

TECHNICAL MANAGER

mv. Cugu

M V TAMIL VANNAN
DY. MANAGER - MICROBIOLOGY

Approved by

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 30/03/2021