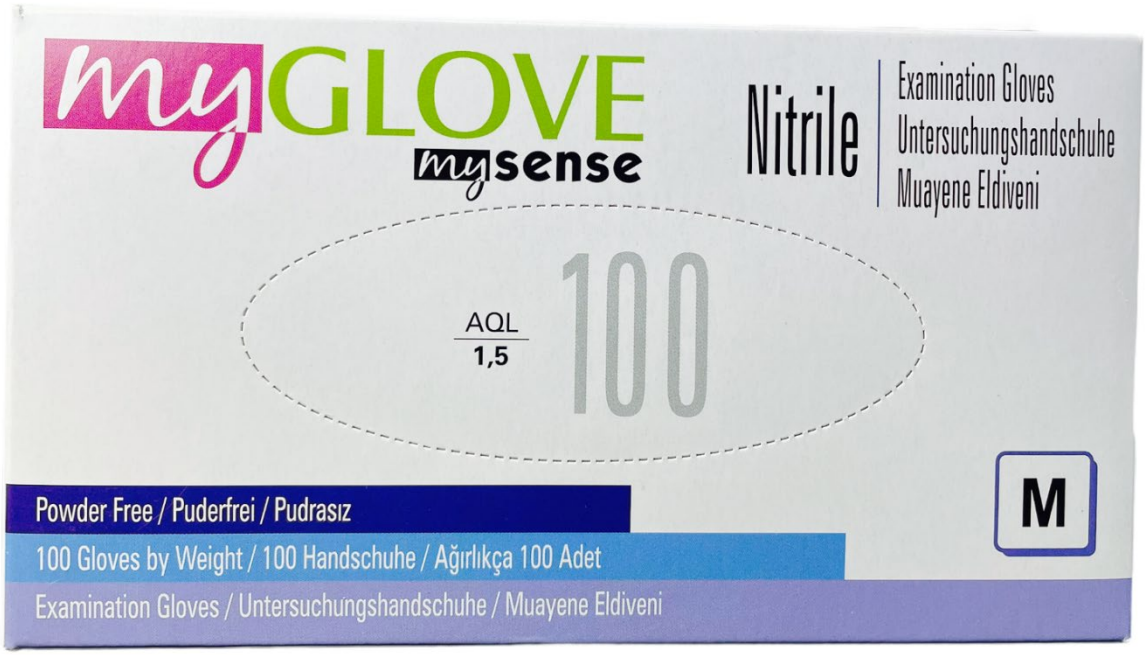
myGLOVE
mysense
Nitrile
Examination Gloves
Untersuchungshandschuhe
Muayene Eldiveni
AQL
1,5
100
M
Powder Free / Puderfrei / Pudrasız
100 Gloves by Weight / 100 Handschuhe / Ağırlıkça 100 Adet
Examination Gloves / Untersuchungshandschuhe / Muayene Eldiveni


myGLOVE
mysense
Nitrile
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Nitrile
M
Powder Free / Puderfrei / Pudrasız
100 Gloves by Weight / 100 Handschuhe / Ağırlıkça 100 Adet
Examination Gloves / Untersuchungshandschuhe / Muayene Eldiveni
myGLOVE
www.my-glove.com
EN
100% Nitrile. Does not contain Natural Latex.
For Single use only. Non-sterile.
Store in a dark and dry place.
Protect from heat, humidity and sunlight.
DE
Nitril 100%. Latexfrei.
Einmalhandschuhe. Nicht steril.
Schützen vor Hitze, Feuchtigkeit und
Sonnenlicht. Dunkel und trocken lagern.
TR
%100 Nitril. Lateks içermez.
Tek kullanımlıktır. Steril değildir.
Kuru ve karanlık yerde saklayınız.
Isı, ışık ve nemden uzak tutunuz.
Please inspect the product before use and dispose if damaged.
Made in Malaysia
Cat. No. MYH-N2-M
8 681406 368288
Hand Size 6(XS) 7(S) 8(M) 9(L) 10(XL)
Median Palm Width ±4mm 76 86 98 107 115
Manufactured for:
LABMARKER DIS TIC. LTD. STI.
Istasyon Yolu Sok. No:3 Altintepe Maltepe
Istanbul TURKEY
+90 216 988 60 15
LATEX
LOT
1101252
191225202176
2019-12
2022-12

Hartalega

Innovation & Quality

DECLARATION OF CONFORMITY

MANUFACTURER:	Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor, Malaysia
EUROPEAN REPRESENTATIVE:	Medical Device Safety Service (MDSS) Schiffgraben 41, 30175 Hannover, Germany
PRODUCT:	Nitrile Powder Free Examination Gloves
CLASSIFICATION:	Class I, according to Annex IX of Directive 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES, ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	Refer to Attachment
START OF CE-MARKING:	November 15, 2014
PLACE, DATE OF ISSUE:	Hartalega NGC Sdn. Bhd., 18th July 2016

SIGNATURE:

NAME: KUAN EU JIN
POSITION: QUALITY MANAGEMENT REPRESENTATIVE

ATTACHMENT 1

Standard	Title
ISO 9001:2008	Quality Management System – Requirement
EN ISO 13485:2012+AC:2012	Medical Device – Quality Management System – Requirement for Regulatory Purpose
EN 455 – 1:2000	Medical Device for Single Use Part 1: Requirement and Testing for Freedom from Holes
EN 455 – 2:2009+A2:2013	Medical Device for Single Use Part 2: Requirement and Testing for Physical Properties
EN 455 – 3:2006	Medical Device for Single Use Part 3: Requirement and Testing for Biological Evaluation
EN 455 – 4:2009	Medical Device for Single Use Part 4: Requirement and Testing for Shelf Life Claim
BS EN 1041:2008	Information Supplied by the Manufacturers with Medical Devices
ASTM D6319 – 10	Standard Specification for Nitrile Examination Gloves for Medical Application
BS EN ISO 14971:2012	Risk Management for Medical Devices
ISO 15223 – 1:2012	Medical devices – Symbol to be Used with Medical device Labels, Labeling and Information to be Supplied Part 1: General Requirement
ISO 10993 – 1:2009/Cor1:2010	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management System
ISO 10993 – 5:2009	Biological Evaluation of Medical Devices Part 5: Test for In Nitro Cytotoxicity
ISO 10993 – 10:2010	Biological Evaluation of Medical Devices Part 10: Test for Irritation and Delayed – Type Hypersensitivity
ISO 2859 – 1:1999	Sampling Procedures and Tables for Inspection by Attributes

Hartalega

ORIGINAL

Document Title
Preshipment Inspection.
Document Number
FN QA 12.0

Revision Number
7
Effective Date
11/01/2019

Inspection Date: 11/05/2020	**Buyer: LABMARKER DIS TICARET LTD. STI.**
PO No: 1105110 (LBMK 02/20) Lot No: 1105110	**Trademark: My Glove My Sense**

CONSIGNMENT DETAILS AND SAMPLING

Size	S	M	L				Total
Article/ Ref / Code No	N/A	N/A	N/A				-
Lot Size	20 box(es) per carton				100 gloves per box		
Gloves	260,000	1,700,000	1,938,000				3,898,000
Cartons	130	850	969				1,949
Sampling Carton	8	20	20				48
Sample size, gloves							
Watertight	80	125	125				330
Visual	80	125	125				330
Dimension	13	13	13				39
Physical property	13	13	13				39
Gloves count per box	2	2	2				6

Carton Numbers Sampled :

S	02	124	71	99	59	47	85	26		
M	06	784	831	372	412	201	222	101	46	139
	591	325	288	493	652	549	442	545	753	714
L	39	165	521	553	678	637	592	763	930	812
	840	881	65	231	301	256	425	441	98	367

REMARKS :

QA PASSED
FOR RELEASE
Initial:
Name / Title : NORHAFIZAH HANIM BAHARUDIN
Date: 11/05/2020 ASSISTANT MANAGER - QA
ID NO. : 200892

HARTALEGA NGC SDN BHD 964586-P

Approved By
Nurul Aisyah Kong
Date
31/12/2018

Hartalega

Document Title
Preshipment Inspection.
Document Number
FN QA 12.0

Sampling Plan

☐ Single	☑ Normal
☐ Double	☐ Tightened
☑ Multiple	☐ Reduced

Revision Number
7
Effective Date
Refer to page 1

PO No: 1105110 (LBMK 02/20)
Trademark: My Glove My Sense

1. WATERTIGHT TEST		
Inspection Level : G1	AQL Level : 1.5	Test method base on : EN 455-1

Conducted by / date: Rega, Tika, Sanju & Hem (11/05/2020)

Sample	S			M			L								
Size (pcs)	80			125			125								
Watertight machine number	**PSI P4-WT-M16**			**PSI P4-WT-M17**			**PSI P4-WT-M17**								
Sampling	Ac	Re	Found	Ac	Re	Found	Ac	Re	Found	Ac	Re	Found	Ac	Re	Found
1st	0	5	0	1	7	0	1	7	0						
2nd	3	8	-	4	10	-	4	10	-						
3rd	6	10	-	8	13	-	8	13	-						
4th	9	12	-	12	17	-	12	17	-						
5th	12	13	-	16	19	-	16	19	-						
6th															
7th															
Accept	Rega		\	Tika		\	Sanju		\						
Reject															

Hartalega

Document Title
Preshipment Inspection.
Document Number
FN QA 12.0

PO No: 1105110 (LBMK 02/20)
Trademark: My Glove My Sense

Sampling Plan

☐	Single	☐	Normal
☐	Double	☐	Tightened
☐	Multiple	☐	Reduced

Revision Number
7
Effective Date
Refer to page 1

3. DIMENSION TEST		
Inspection Level : N=13 AQL Level : Median value obtained must meet specifacation set	Sample Size : 13 pcs Accept : - Reject : -	Test method base on : EN 455 Part 2

Conducted by / date: Rega, Tika, Sanju & Hem (11/05/2020)

Size : [ ] Ex-Small [√] Small [ ] Medium [ ] Large [ ] Ex-Large

Sample No.	Overall Length (mm)	Palm Width (mm)	Palm Thickness (mm)	Finger Thickness (mm)	Cuff Thickness (mm)	Beading Thickness (mm)
Ruler / Thickness gauge serial	**PS1-SR-026**	**PS3-SR-051**	**016812**			
1	240	85	0.051	0.094		
2	241	85	0.052	0.070		
3	243	86	0.051	0.077		
4	244	85	0.055	0.086		
5	240	86	0.052	0.090		
6	240	86	0.053	0.077		
7	241	85	0.053	0.085		
8	241	85	0.053	0.087		
9	240	86	0.053	0.075		
10	242	86	0.052	0.079		
11	245	85	0.055	0.085		
12	241	86	0.056	0.084		
13	240	86	0.054	0.079		
Minimum	240	85	0.051	0.070		
Maximum	245	86	0.056	0.094		
Average/Median	241	86	0.053	0.084		
Specification	Min 240mm	86±4mm	Min 0.05mm	0.05 - 0.11mm		
Disposition	Pass	Pass	Pass	Pass		
Accept	√	√	√	√		
Reject						

Approved By
Nurul Aisyah Kong
Date
Refer to page 1

Hartalega

Document Title
Preshipment Inspection.
Document Number
FN QA 12.0

Sampling Plan

☐ Single	☐ Normal
☐ Double	☐ Tightened
☐ Multiple	☐ Reduced

Revision Number
7
Effective Date
Refer to page 1

PO No: 1105110 (LBMK 02/20)
Trademark: My Glove My Sense

6. PHYSICAL PROPERTIES TEST			
Conducted by / date: Moe (11/05/2020)			
Inspection Level : N=13		In compliance with : EN455-2	
Sample size : 13 Pieces		Median value obtained must meet specification set	
SIZE	Machine serial number	Force at Break (N) before aging	Force at Break (N) after aging
Extra-Small			
Small	**I33065434565CS**	6.23	
Medium	**I33065434565CS**	5.47	
Large	**I33065434565CS**	5.90	
Extra-Large			
Specification		≥ 4	≥ 4

DISPOSITION :	Extra-Small	Small	Medium	Large	Extra-Large
ACCEPT /	N/A	√	√	√	N/A
REJECT					

Approved By
Nurul Aisyah Kong
Date
Refer to page 1

SATRA TECHNOLOGY

Notified Body 0321

Issued to: **LABMARKER DIS TIC LTD STI**
Istasyon Yolu Sok. No. 3
34840 Altintepe Maltepe
Istanbul
TURKEY

SATRA Client : P1144

EC Type-Examination Certificate

Number 7726 Issue 3 Extension 9

This is to certify that the product group reference "My Glove Nitrile Examination Glove" comprising the following products:

Product Reference	**Description**
My Glove Nitrile Examination Glove	Powder free Blue Nitrile disposable five fingered glove

Sizes:6 (XS) to 10 (XL)

Classification:

EN 388:2003	**Level**
Abrasion resistance	0
Blade cut resistance	0
Tear resistance	0
Puncture resistance	0

EN 374-1:2003	**Level**
Sodium Hydroxide 40%	6

EN 374-2:2003	
Air leak	Pass
Water Leak	Pass

Technical reports:
SATRA: CHM0210704/1301/RS, CM0227109/1431/EN, SPC0232012/1505 Issue 2, CHM0231968/1505/EN, CHM0236408/1528/DRWM

has been subject to an EC Type-examination in accordance with Article 10 of the PPE Directive (89/686/EEC) and has been shown to satisfy the relevant provisions of this Directive for the complex category through:

i Testing to the following standard:
EN 374-1: 2003 excluding clause 5.3.2; EN388: 2003; EN 420: 2003+ A1: 2009
ii Examination of the relevant technical documentation.

You are therefore licensed to mark the product(s) listed above in accordance with Article 13 of Directive (89/686/EEC) and any relevant amending Directives once you have drawn up an EC declaration of product conformity. Please note that:

1. Full details of the certification and product are contained in the manufacturer's technical file
2. This certificate is issued subject to the conditions on the reverse side of this certificate
3. CE Marking of production is also reliant on current compliance with Directive 89/686/EEC Article 11
4. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text

Signed: (Camille Lu) Date 05/02/2018

Signed:

On behalf of SATRA