

**BEST IN
CLASS**

HanSoft



St Luke 
LIFE SCIENCES

HIGH QUALITY
NITRILE GLOVES



POWDER FREE NITRILE DISPOSABLE EXAMINATION GLOVES



HanSoft nitrile disposable gloves are manufactured from high quality acrylonitrile butadiene rubber. Our gloves adhere to stringent uncompromising quality control specifications as per reputed international standards. The gloves have been designed for use in a variety of sectors with special emphasis on the healthcare industry. Our gloves have been designed to minimize tackiness and to provide better grip, comfort.

They offer greater chemical resistance and higher tensile strength in comparison to the traditional latex and vinyl counterparts. Moreover, nitrile gloves eliminate risk to latex allergy whilst maintaining excellent tactile sensitivity and dexterity. Textured surface of the gloves promotes nimble handling of materials and instruments.



Description: Medical examination gloves are used for preventing contamination between caregivers and patients. These gloves are used during procedures that do not require sterile conditions: drawing blood for a blood test being an example. Some of these gloves also protect the wearer from harm caused by dangerous chemicals and pharmaceuticals.

Intended Use: Medical examination gloves are used for preventing contamination between patients and healthcare providers.



In Compliance with:

- European Medical Device Directive 93/42/EEC (Class 1)
- CE Certified
- FDA and FDA 510k Registered
- Type tested to EN 455-1,2,3,4
- ASTM D6319 & ASTM D3578(2)
- MDA

Type	Powder free, non-sterile
Material	Acrylonitrile Butadiene Rubber
Colour	Blue (Standard). Other Colors can be customised on request
Design & Features	Finger texture, Palm Texture, Beaded and Powder free
Size Range	X-Small, Small, Medium, Large, X-Large
Storage	Store in a cool, dry place, avoid excessive heat (40°C, 104F). Open box should be shielded from exposure to direct sun or fluorescent lighting.
Quantity and Standard	EN455-1, 2, 3, 4 and ASTM D6319, ASTM D3578(2)

POWDER FREE NITRILE DISPOSABLE EXAMINATION GLOVES

DIMENSIONS & PROPERTIES

Length (mm)	≥ 300	
Thickness Measurements (mm)		
Finger:	Min. 0.15	
Palm (centre of palm) :	Min. 0.09	
Cuff:	Min. 0.05	
Physical Properties:	Before Ageing	After Ageing
Tensile Strength (MPa)	≥ 14	≥ 14
Elongation (%)	≥ 500	≥ 400
Inspection Levels & AQL	Inspection Level	AQL
Watertightness	G1	1.5
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Visual Inspection (Major)	S4	2.5
Visual Inspection (Minor)	S4	4.0
Particulate Residue	N = 5	≤ 2mg/glove



Made In Malaysia

Marketed by :

St. Luke Lifesciences Pvt. Ltd.

Plot No:1-A,2,3(Part), 8th Street,
Balaji Nagar, Nerkundram,
Chennai-600107, India.

HanSoft 

CARTON BOX



NITRILE Examination Gloves
POWDER FREE - NON STERILE
AMBIDEXTROUS - SINGLE USE ONLY




CERTIFICATE OF COMPLIANCE –
EU DECLARATION OF CONFORMITY**EU DECLARATION OF CONFORMITY**

Manufacturer Name	: WORLDEX MEDIC SUPPLIES SDN BHD (1376223-P)
Address	: 9, Jalan Puteri 5/18, Bandar Puteri Puchong, Puchong, Selangor, Malaysia.
Name of Medical Device	: (1)-Nitrile Examination Gloves : (2)-Natural Latex Examination Gloves
Features	: ambidextrous with rough / textured fingertips and rolled-edge cuffs
Conformity Route	: Self Declaration
Quality Management System	: ISO 13485:2016
Packing Centre QMS	: ISO 9001:2015
SGS Test Report	: EN 455 (1/2/3/4) : ASTM D6319 (1) / ASTM D3578 (2)

We, hereby declare that the devices as listed above meet the applicable provisions of the medical device(s) Directive 93/42/EEC, and the product conforms to EN 455 directive.

Validity of this Declaration is from **28-04-2021** till **27-04-2024**

Certified and Issued by,


Abby V.S.

Euro Certification & Inspection Ltd



WORLDEX MEDIC SUPPLIES SDN BHD (1376223-P)
9, Jalan Puteri 5/18, Bandar Puteri Puchong, Puchong, Selangor, Malaysia.
Tel: +603 8066 9825 ; Email: jerel@worldexasia.com

**CERTIFICATE OF COMPLIANCE –
 FDA U.S FOOD AND DRUG ADMINISTRATION (LZA)**


2021
FDA CERTIFICATE OF REGISTRATION

This certifies that:
WORLDEX MEDIC SUPPLIES SDN. BHD.
No.9, Jalan Puteri 5/18 ,
Bandar Puteri Puchong,
47100 Selangor,Malaysia.

has been registered and has listed the following medical device with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	10081878
Device Classification Name:	LATEX / NITRILE EXAMINATION GLOVE
Product Code	LZA, LYY, IWP
Regulation Number:	880.6250
Official Correspondent:	Dato' Jerel
	No.9, Puchong, Selangor, MY 47810
	Phone: 60122771252 ; Email: datojerel@gmail.com

Euro Certification and Inspection Ltd will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above. Euro Certification and Inspection Ltd makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole establishment by the U.S. Food and Drug Administration. Euro Certification and Inspection Ltd assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Euro Certification and Inspection Ltd is not affiliated with the U.S. Food and Drug Administration



EURO CERTS LLC
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Abby V.S.
Abby V. S.
Executive Director
Euro Certs
Dated: 05 July 2021

SGS

JOB REF NO. : 2020-04-02-003
 DATE RECEIVED : APR 02, 2020
 DATE REPORTED: APR 15, 2020
 PAGE: 1 of 4

Test Report No. : CRSSA/200437126-CA36672
 Company :

TEST REPORT

Sample Description : Nitrile Examination Powder Free Glove
 Other Detail : RA/031/02/2020/D1
 Size : Medium
 Quantity Tested : 200 pieces
 Test Conducted : Freedom from holes
 Test Method : EN455 Part 1:2000
 Testing Period : 02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 2

Result : Within AQL

SIGNED FOR AND ON BEHALF OF
 SGS (MALAYSIA) SDN BHD



CHEE TUCK CHOON
 SECTION HEAD
 IKM No. M/3983/6401/12/14

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SGS (Malaysia) Sdn Bhd
 (Company No. 18871-T)

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JOB REF NO. : 2020-04-02-003
DATE RECEIVED : APR 02, 2020
DATE REPORTED: APR 15, 2020
PAGE: 3 of 4

Test Report No. : CRSSA/200437126-CA36672
Company :

TEST REPORT

Sample Description : Nitrile Examination Powder Free Glove
 Other Detail : RA/031/02/2020/D1
 Size : Medium
 Quantity Tested : 13 pieces per each
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 168 hrs
 Testing Period : 02 Apr 2020 – 15 Apr 2020

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
M	1	8.1	6.7
	2	7.4	6.4
	3	7.4	8.3
	4	7.7	6.3
	5	7.8	7.4
	6	8.3	7.6
	7	8.4	6.6
	8	6.4	8.4
	9	7.8	8.7
	10	9.0	6.5
	11	8.4	8.7
	12	8.0	7.3
	13	7.9	6.2
Median		7.9	7.3
Requirement		≥ 6.0	≥ 6.0

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DATE RECEIVED : APR 02, 2020
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PAGE: 2 of 4

Test Report No. : CRSSA/200437126-CA36672
Company :


TEST REPORT

Sample Description : Nitrile Examination Powder Free Glove
 Other Detail : RA/031/02/2020/D1
 Size : Medium
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	92	92	94	92	93	94	93	92	92	92	93	92	92	92
Length Median: ≥ 240mm	256	256	253	260	259	258	254	260	254	251	256	251	254	256

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LET US GROW TOGETHER



We sincerely appreciate your support in expanding our business



For more information and clarifications, please contact our Directors

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