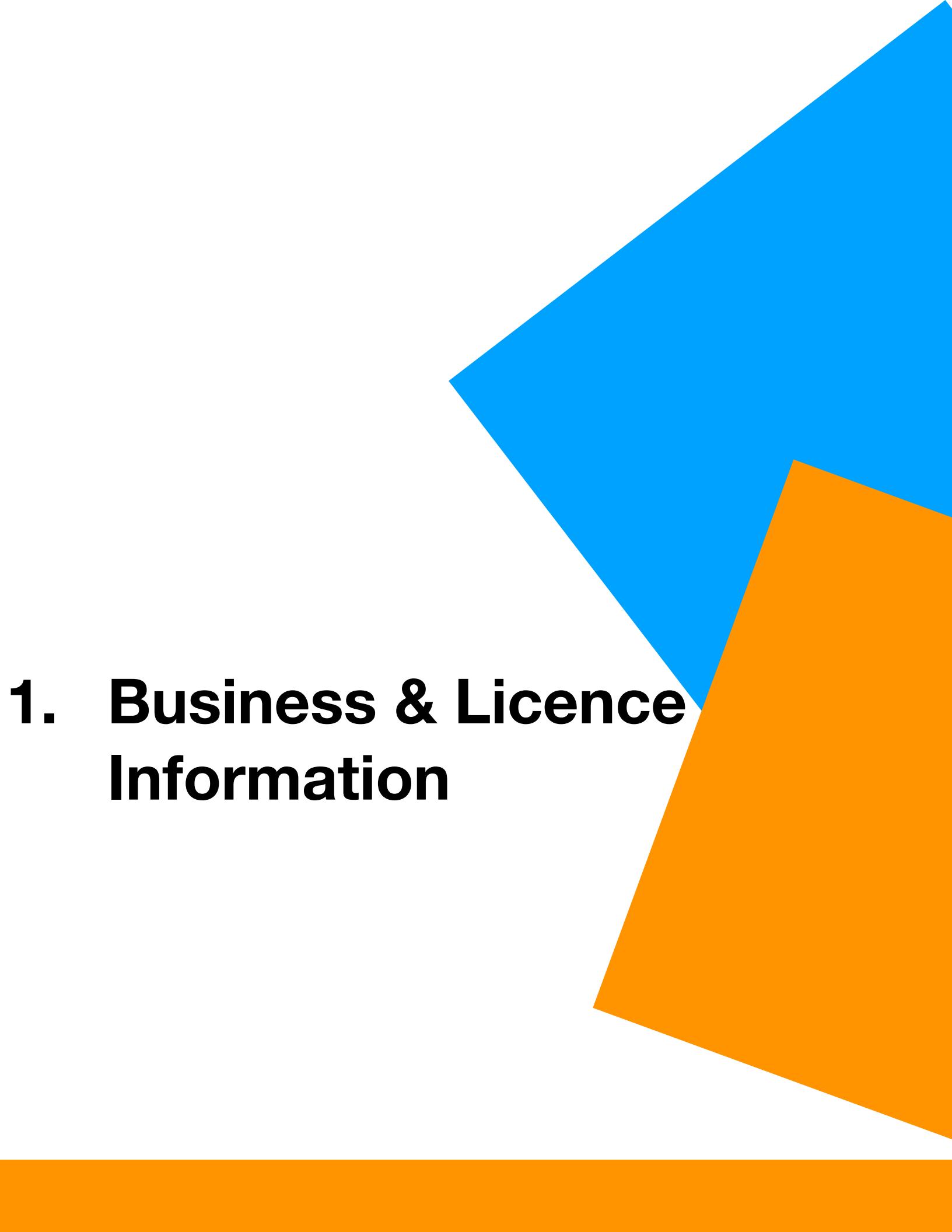


# **Digital Mi'kmaq Health Binder**

**v 1.0**

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# **1. Business & Licence Information**

# **Important Legal Information:**

**HS Code:** 63007/8471

**Buy And Sell Number:** 54368

**Business Procurement Number:** 105439327

**Supplier User Name:** Digital Mi'kmaq

**Password:** DM 1234!

# Digital Mi'kmaq MDEL Licence Number: 11778

Licence Number

**11778**

Numéro de la licence

**Medical Device  
Establishment Licence**

**Licence d'établissement  
pour les instruments médicaux**

## **DIGITAL MIKMAQ**

5121 SACKVILLE STREET  
SUITE 401  
HALIFAX, NOVA SCOTIA  
CANADA  
B2J 1K1

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	<b>Distributor / Distributeur</b>	<b>Importer / Importateur</b>	<b>Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution</b>
Class I / Classe I	No / Non	Yes / Oui	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

**Attestation made :**

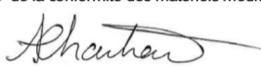
**Attestations faites :**

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:
• distribution records	[Y]	• les registres de distribution
• complaint handling	[Y]	• les plaintes
• recalls	[Y]	• les rappels
• mandatory problem reporting	[Y]	• rapports d'incident obligatoires
• handling, storage, delivery	[N]	• la manutention, le stockage, la livraison
• installation	[N]	• l'installation,
• corrective action	[N]	• les mesures correctives
• servicing	[N]	• l'entretien

**Site listing begins on the back of this page**

**Liste des sites commence au verso de cette page**

Issue Date, date de délivrance: 2020-03-30

Minister of Health Ministre de la santé	Countersigned: Director, Medical Devices Compliance Program or delegated authority Contresigné par: Directrice, Programme de la conformité des matériaux médicaux ou autorité déléguée   Anik Michelle Chartrand
--	---

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.  
Cette licence appartient au Programme de la conformité des matériaux médicaux et doit être renvoyée sur demande.

## **2. PPE Delivery Process**

# **Digital Mi'kmaq's PPE Delivery Service Terms and Conditions Handing, Storage And Delivery.**

All items being delivered under Digital Mi'kmaq PPE Delivery Service are free of charge. That includes shipping, we **do not** ship to PO Boxes.

All orders for front-line health professionals in our Health boxes are being shipped by Canada Post's ground service on a regular basis.

All imported items are shipped directly to our office in Halifax and sanitized before they are placed in health boxes that are sent out. These include medical grade gloves and KN95 respirators.

The same sanitizing process is followed for manufactured face shields in our office, all individual parts are sanitized before they are put in the boxes.

All PPE is stored in our main office that is regularly cleaned and sterilized. The office staff obeys the rules social distancing and uses required PPE when handing products.

A shipment goes out every Thursday, and depending on the location takes **5-7 business days** on average.

The Products being shipped are for front line health professionals working in Reserve communities.

The PPE quantities we are providing for Health Centres on Reserves and Front Line Health Professionals include: **25 Face Guards, 25 KN95 Face Shields and 25 Surgical Gloves.**

## **RETURN POLICY**

All returns must be made within 30 days from the date of delivery and include the original packaging.

All returns must obtain return authorization first to ensure they have not been contaminated.

Returns must be accompanied by a copy of the shipping document and dates when they were delivered so as to not confuse our shipment with others.

## **APPLICABLE LAWS**

1. These Terms and Conditions are subject to Nova Scotia Provincial Laws as well as Federal in regards to Health Canada and our MDEL licensing.
2. Any dispute arising from the execution or interpretation of the provisions of this contract requires the parties to come together and to try to find an amicable solution.
3. Digital Mi'kmaq is producing and delivering these resources to Indigenous Communities as a **Gift**.

# **Complaint Handling**

Digital Mi'kmaq is dedicated to providing excellent customer service and maintaining a healthy relationship with end users.

We have a Complaints Policy to ensure all complaints are handled as efficiently and effectively as possible.

As a customer of ours, you are entitled to make a complaint to us. The following outlines our policy and procedures for the handling of verbal and written complaints

## **Summary:**

We want to resolve your complaints as soon as possible. Please call our customer service and we'll do our best to fix any problems you may be having with our service, as soon as possible.

## **Our Responsibilities:**

- To provide an efficient, fair and structured mechanism for handling complaints.
- To provide our customers with access to the complaints handling process, including those customers with disabilities and special needs.
- To keep customers informed as to the progress of their complaint and the expected timeframe for resolution.
- We will keep you informed of the progress of your complaint, proposed actions and the expected timeframe for resolution.

- We will advise you of the outcome of your complaint. Where you have requested us to do so, we will advise you in writing.
- Making a complaint should normally be free. If we think your complaint requires a charge, we will not impose one without discussion with you.
- Use e-mail or phone to send us any of your inquiries.

E: [info@digitalmikmaq.com](mailto:info@digitalmikmaq.com)

P: 902-406-0979

## Mandatory Problem Reporting

In case of an incident that:

- occurs either within or outside Canada;
- relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use and
- has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur

Digital Mi'kmaq will report to Health Canada by filling up the *Mandatory Problem Reporting Form For Industry* under Medical Device Problem Reporting Program (CV-MD).

## **Instructions:**

Report of problems related to medical devices marketed in Canada

### **CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM (CV-MD)**

#### **How to Submit the Report**

Completed forms should be

**emailed to:** [hc.mdpr-dimm.sc@canada.ca](mailto:hc.mdpr-dimm.sc@canada.ca)

or

**faxed** to: 613-954-0941

#### **Mailed to:**

Canada Vigilance - Medical Device Problem Reporting Program  
Marketed Health Products Directorate  
Health Canada  
Address Locator 1908C

200 Tunney's Pasture Driveway Ottawa (Ontario) K1A 0K9

*Submission of a report does not constitute an admission that medical personnel or the health product caused or contributed to the incident.*

## A. REPORTER INFORMATION

This section contains information about the reporter, who is submitting the report to Canada Vigilance – Medical Devices Problem Reporting Program (CV-MD) to fulfil their obligations under sections 59, 60, 61 and 61.1 of the *Medical Devices Regulations*. It also includes details about the manufacturer and importer of the medical device that are responsible to submit the report to CV-MD.

**A1. Reporter Type:**

- i. Indicate if the reporter submitting this report to CV-MD is the manufacturer or the importer.
- ii. Indicates if the importer submitting this report to CV-MD has also submitted reported this problem to the manufacturer of the device.
- iii. Indicates if the importer is submitting on behalf of the manufacturer.

**A2. Reporter Contact Information:** Includes the name of the individual, email, telephone and fax number of the reporter or his/her representative.

**A3. Reporter File Number:** Indicates the manufacturer's or importer's file number for the case. For final reports, the report number should be the same as the preliminary report.

**A4. Health Canada File Number:** A number provided in the acknowledgement letter for the preliminary report. It's a unique number assigned by Health Canada for the report.

**A5. Type of Report:** Indicates if the report being submitted is a preliminary, update, final, or a preliminary and final. It also includes the anticipated date for the submission of the final report.

**A6. Date Submitted:** Indicates the date at which the report is being submitted by the manufacturer/importer to CV-MD.

**A7. Name and Address:** Indicates the name and address of the manufacturer and importer of the medical device.

**A8. Health Canada assigned company identification number (if known):** The company identification number can be found either on the medical device licence or on the medical device establishment licence, as appropriate.

**A9. Establishment Licence Number (if applicable):** Indicates the establishment licence (MDEL) number of the manufacturer and importer of the medical device in Canada.

## **B. INCIDENT INFORMATION**

This section contains information about the incident that occurred with the medical device requiring a mandatory problem report to be submitted to CV-MD. It includes details about the incident and the patient consequences that occurred/could have occurred. In the context of mandatory problem reporting, information on the incident refers to the circumstances requiring reporting under section 59 of the *Medical Devices Regulations*.

**B1. Classification of Incident:** Indicates

- i. if the report is a 10 day or 30 day report, based on the seriousness of the incident associated with the medical device
- ii. whether the incident occurred inside or outside Canada
- iii. whether the incident occurred during investigational testing, or was caused by a medical device available only through the special access program or is a radiation emitting device (RED).

**B2. Date of Incident:** Indicates the date at which the incident with the medical device occurred.

**B3. Reporter's Awareness Date:** Indicates the date at which the manufacturer/importer of the medical device became aware of the potential problem associated with the device.

**B4. Patient Consequences:** Includes information on the patient who was involved in the incident, and the consequences (or potential consequences) to the patient, user or other person(s) involved.

**B5. Details of Incident:** Includes description of device(s), equipment, or drugs involved in the incident, and a detailed description of what happened in the incident.

## C. MEDICAL DEVICE INFORMATION

This section contains details about the medical device involved in the incident, including its brand name and licence number.

- C1. Trade/Brand Name:** Indicates the trade/brand name of the device and reported on the label.
- C2. Control/Lot/Serial #:** Indicates the control number, lot number and/or serial number for the device.
- C3. Expiration Date:** Indicates the expiration date issued to the medical device (if applicable).
- C4.**
  - i. Device Classification:** Indicates the class of the device (I-IV).
  - ii. Device Licence Number:** Indicates the medical device licence number issued by the Medical Devices Bureau on behalf of the Minister for Class II, III and IV medical devices sold in Canada.
  - iii. Device Identification No:** Indicates the device identification number assigned by Health Canada in the license issued for the device.
  - iv. Manufacturer's Medical Device Identifier:** Indicates the unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a catalogue, model or part number.
- C5. Software Version:** Indicates the version of the software contained within the device, if applicable for the device.
- C6. Age of Device:** Indicates the number of years since the manufacturing date of the device.
- C7. How long was the device in use?** Indicates how long the device was used.
- C8. Was the device labelled as sterile?** Indicates if the device sold was manufactured and packaged in sterile conditions.
- C9. Availability of Device:** Indicates if the device has been destroyed, or is available for the company/Health Canada for further evaluation to determine the root cause of the failure associated with the device.

## **D. COMPLAINANT INFORMATION**

This section contains information about the complainant that contacted the reporter to inform them about the incident.

- D1. Complainant is a:** Indicates if the complainant reporting to the manufacturer/importer was a consumer, a health professional etc.
- D2. Name of Complainant:** Indicates the name of the person who informed the reporter about the incident.
- D3. Name of Health Care Facility:** This section indicates the name of the health care facility where the problem occurred.
- D4. Address:** Indicates the complete address of the complainant, including the postal code.
- D5. Contact Information:** Indicates the telephone number and/or email address of the complainant.

## **E. INVESTIGATION INFORMATION**

This section contains information about the investigation being carried out by the manufacturer/importer of the medical device to determine if there's any problem with the medical device, and if any corrective actions are necessary.

- E1. Investigative Actions and Timeline:** Includes the rationale for the course of action taken to investigate the incident, the details of the action to be completed, and the timeline for its completion. If no investigation is to be done, a rational needs to be provided here.
- E2. Root Cause of Problem:** To be completed once the investigation of the incident is complete, and the root cause of the incident identified. The root cause would ascertain the most likely reason why the problem occurred with the medical device. This section only applies for final reports.
- E3. Corrective actions taken as a result of the investigation:** Includes information on actions taken to correct the problem, including any post-market surveillance, recalls, or corrective or preventive actions and the design and manufacture of the device. This should also include the rationale for performing the corrective action. This section only applies for final reports. If no corrective action is to be taken, a rationale needs to be provided here.



## Mandatory Medical Device Problem Reporting Form for Industry

### CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets  
Fields required to be completed for updates/final reports are indicated by an \*

Page \_\_\_\_ of \_\_\_\_

#### A. REPORTER INFORMATION

1. i. Reporter Type

Manufacturer       Importer

*In the case where the reporter is the importer:*

ii. Did the importer report the incident to the manufacturer?

Yes       No

iii. Is the importer also submitting the report on behalf of the manufacturer?

Yes       No

2. Reporter Contact Information \*

3. Reporter File No. \*

4. Health Canada File No. (if applicable) \*

5. Type of Report \*

Preliminary       Update       Final       Preliminary & Final

If "preliminary" only, anticipated date for the final report:

(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

(YYYY-MM-DD)

6. Date Submitted \*

(YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address		
8. Health Canada assigned company identification number (if known):		
9. Establishment License Number (if applicable):		

#### B. INCIDENT INFORMATION

1. Classification of Incident \*

i.  10-Day       30-Day  
 ii.  Canadian       Foreign  
 iii.  Investigational testing       Special Access Program  
 Radiation emitting device (if applicable)

5. Details of Incident

2. Date of Incident

(YYYY-MM-DD)

3. Reporter's Awareness Date

(YYYY-MM-DD)

4. Patient Consequences

**C. MEDICAL DEVICE INFORMATION**

1. Trade/Brand Name \*

2. Control/Lot/Serial No.

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

 I    II    III    IV

ii. Device License No.

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier  
(catalogue/model no.)

5. Software Version

6. Age of Device

7. How long was the device in use?

8. Was the device labelled as sterile?

 Yes    No

9. Availability of device for evaluation

 Destroyed    Returned to Manufacturer/Importer  
 Neither (with explanation)**D. COMPLAINANT INFORMATION**

1. Complainant is a:

 Consumer    Health professional    Other

2. Name of Complainant

3. Name of Health Care Facility (if applicable)

4. Address

5. Telephone No. and/or E-mail Address

**Privacy Notice Statement:** For the purposes of the Canada Vigilance -Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: <https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a25>

**E. INVESTIGATION INFORMATION**

1. Investigative Actions and Timeline

This section only applies for preliminary &amp; final, and final reports

2. Root Cause of Problem

3. Corrective Actions taken as a result of the investigation

## Recalls

Digital Mi'kmaq's Recall Plan outlines the activities that our company will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. Our Company's recall plan shall be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change.

VERSION: \_\_\_\_\_

Approved by:

Date approved:

### Recall Actions:

**A. First 24 Hours:** Digital Mi'kmaq has the responsibility to recall product in a clear and timely manner. We will make all reasonable efforts to remove affected products from commerce. Any products that are still in our control (inventory, in transit or in offsite distribution) will be detained and segregated. Identification codes and quantities will be documented to assist in the reconciliation or product amounts. Digital Mi'kmaq is responsible for determining whether the recall is effective and will verify that all customers have been notified.

1. Digital Mi'kmaq will notify the appropriate regulatory agencies.
2. Digital Mi'kmaq will prepare a customer distribution list indicating where recalled product was shipped to.

3. Digital Mi'kmaq will notify all customers that received recalled product(s). The method of notification of customers will be determined by the severity of the recall. The quickest way to reach customers is by telephone. Digital Mi'kmaq will provide clear information on the product, the problem and what we need customers to do. Written recall notice will be provided to all customers who received recalled product(s) as well.
4. If necessitated, Digital Mi'kmaq will notify consumers of the recall. This can include a press release communication methods can include posting notification on social media sites, web sites and in stores in a location where product is sold.
5. For situations where the recalled product may pose a significant health hazard, the recall coordinator will file a mandatory problem reporting form and send it to Health Canada.

## **B. Product Recovery and Disposal:**

1. Digital Mi'kmaq will control all affected product. Any returned product will be clearly marked not for sale or distribution and will be stored in an area that is separate from any other food products.
2. Any disposition or reconditioning of product may need to be documented and/or approved by Health Canada.
3. Digital Mi'kmaq will also work with the appropriate local health jurisdictions agencies to determine a safe way to dispose of product.
4. All quantities and identification codes of disposed items will be recorded.

5. Digital Mi'kmaq will work with the communities to reconcile the volume of recalled product produced with the volume of recalled product on hand and returned.

**C. Recall Effectiveness Checks:** Digital Mi'kmaq is responsible for determining whether the recall is effective. We will verify that all customers have received notification and that they have taken appropriate action. We will confirm receipt of the Notice of Recall with all accounts.

**D. Recall Actions:** Termination of Recall: Termination of the recall is considered after all reasonable efforts have been made to remove the recalled product from commerce, including reconciliation, recall effectiveness and disposition. Digital Mi'kmaq will issue a report to Health Canada as to the reason for the recall and the corrective action steps to prevent this from happening again.

# **Digital Mi'kmaq Recall Notification**

**< Insert Product.>**

**RECALL Date:**

**Contact Name:**

**Firm's Name:**

**Address:**

**City:**

**State:**

**Phone number:**

Dear < >: This is to inform you of a product recall involving:  
Insert: PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC  
CODES, LOT NUMBERS

See enclosed product label . This recall has been initiated due to <Problem> . Use of this product may . We began shipping this product on (or). This product was shipped to you on <Date> . (provide with shipping dates and quantities shipped.)

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Customers are advised to (e.g. destroy, return, hold for pick up). If you re-label, re-pack, or use the recalled products to produce new products, please contact the State Recall Coordinator in your state.

Your assistance is appreciated and necessary to prevent any damage that may be caused by using the recalled product. Please complete and return the enclosed response form as soon as possible. If you have any questions contact us via e-mail or phone.

## Digital Mi'kmaq Recall Records

Date: Begin & End	Product	Comments



### **3. Canada Post Account**

## **Digital Mi'kmaq Canada Post Account**

**Business Number:** 0009013233

**User Name:** Digital Mi'kmaq

**Password:** M1ntreal!

A large, light gray rectangular area contains the section title. In the top right corner, there is a large blue triangle pointing towards the center. Below it, a large orange triangle points towards the center from the bottom right.

## **4. Receiving Records And Invoices**



**Store links:** <https://yixintrading.en.alibaba.com/>

Room A410, Jinjiang Wuli E-commerce industry park, No.6 Xiangyuan Road, Quanzhou,Fujian.

Tel: 0595 8208 1581 Mob: +86 13489520889 E-mail:kelly@qzyixincn.com

### PROFOMA INVOICE

**TO: Seyit Tumturk/Digital Mikmaq**

**licence number : 11778**

**Contact number:** 19024415931

**Office address :** 5121 Sackville Street, Suite 401 Halifax, NS, B3J 1K1

NO.	Model Number	description	Picture	Specification	Quantity(pc)	Price	EXW-Price(USD)
1	YXIN	KN95 Mask		KN95 Mask	5000	1.25	6250.00
Air cargo special line door to door including taxes and clearance, Freight: \$1388.9 Delivery time: 7-10 work days							1388.90
<b>summation</b>				5000			7638.90
I declare that all the information contained in this invoice is true and correct. Payment: Pay 100% before production.							
<b>TOTAL</b>							7638.90



## Track DHL Express Shipments

Here's the fastest way to check the status of your shipment. No need to call Customer Service – our online results give you real-time, detailed progress as your shipment speeds through the DHL network.

### Result Summary

**Waybill: 2414792715**

**Processed for clearance at ONTARIO SERVICE AREA - CANADA**

**Tuesday, May 12, 2020 at 11:55**

**Origin Service Area:**

GUANGZHOU - GUANGZHOU - CHINA MAINLAND

**Destination Service Area:**

NOVA SCOTIA AREA, NS - HALIFAX - CANADA

The Estimated Delivery Date is currently unavailable. Please try again later.

5 Pieces

<b>Tuesday, May 12, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
47	Processed for clearance at ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	11:55	
<b>Wednesday, April 22, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
46	Scheduled for delivery as agreed	NOVA SCOTIA AREA, NS - CANADA	09:54	
45	With delivery courier	NOVA SCOTIA AREA, NS - CANADA	08:44	1 Pieces
44	Arrived at Delivery Facility in NOVA SCOTIA AREA - CANADA	NOVA SCOTIA AREA, NS - CANADA	01:23	1 Pieces
<b>Tuesday, April 21, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
43	Shipment held - Available upon receipt of payment	NOVA SCOTIA AREA, NS - CANADA	17:27	
42	Shipment on hold	NOVA SCOTIA AREA, NS - CANADA	09:20	
41	Arrived at Delivery Facility in NOVA SCOTIA AREA - CANADA	NOVA SCOTIA AREA, NS - CANADA	07:06	2 Pieces
<b>Monday, April 20, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
40	Departed Facility in ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	23:37	3 Pieces
39	Processed at ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	12:49	3 Pieces
38	Processed for clearance at ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	10:35	2 Pieces
37	Clearance event	ONTARIO SERVICE AREA, ON - CANADA	10:23	
36	Customs status updated	ONTARIO SERVICE AREA, ON - CANADA	04:46	
35	Arrived at Sort Facility ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	04:14	4 Pieces
34	Customs status updated	CINCINNATI HUB, OH - USA	02:06	
33	Departed Facility in CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	02:27	4 Pieces
32	Processed at CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	01:17	4 Pieces
<b>Sunday, April 19, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
31	Clearance processing complete at CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	23:07	4 Pieces
30	Arrived at Sort Facility CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	19:00	4 Pieces
29	Processed at ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	15:39	1 Pieces
28	Clearance processing complete at ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	15:23	1 Pieces

<b>Tuesday, May 12, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
27	Customs status updated	CINCINNATI HUB, OH - USA	04:49	
<b>Saturday, April 18, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
26	Customs status updated	CINCINNATI HUB, OH - USA	14:58	
25	Departed Facility in HONG KONG - HONG KONG	HONG KONG - HONG KONG	20:46	4 Pieces
24	Arrived at Sort Facility ONTARIO SERVICE AREA - CANADA	ONTARIO SERVICE AREA, ON - CANADA	08:41	1 Pieces
23	Customs status updated	ONTARIO SERVICE AREA, ON - CANADA	08:41	
22	Departed Facility in CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	07:18	1 Pieces
21	Processed at CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	06:34	1 Pieces
20	Processed at HONG KONG - HONG KONG	HONG KONG - HONG KONG	16:58	4 Pieces
19	Clearance processing complete at CINCINNATI HUB - USA	CINCINNATI HUB, OH - USA	04:00	1 Pieces
18	Shipment on hold	CINCINNATI HUB, OH - USA	01:19	1 Pieces
<b>Friday, April 17, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
17	Customs status updated	CINCINNATI HUB, OH - USA	12:20	
16	Departed Facility in HONG KONG - HONG KONG	HONG KONG - HONG KONG	18:18	1 Pieces
15	Processed at HONG KONG - HONG KONG	HONG KONG - HONG KONG	17:00	5 Pieces
14	Clearance processing complete at HONG KONG - HONG KONG	HONG KONG - HONG KONG	12:30	5 Pieces
13	Arrived at Sort Facility HONG KONG - HONG KONG	HONG KONG - HONG KONG	12:07	5 Pieces
12	Shipment on hold	HONG KONG - HONG KONG	10:58	5 Pieces
11	Customs status updated	HONG KONG - HONG KONG	04:02	
10	Departed Facility in GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	03:10	5 Pieces
9	Processed at GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	03:06	5 Pieces
<b>Thursday, April 16, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
8	Clearance processing complete at GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	21:45	
7	Clearance event	GUANGZHOU - CHINA MAINLAND	06:27	5 Pieces
<b>Saturday, April 11, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
6	Shipment on hold	GUANGZHOU - CHINA MAINLAND	05:45	5 Pieces
5	Arrived at Sort Facility GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	05:41	5 Pieces
<b>Thursday, April 09, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
4	Departed Facility in GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	21:56	5 Pieces
3	Processed at GUANGZHOU - CHINA MAINLAND	GUANGZHOU - CHINA MAINLAND	19:04	5 Pieces
2	Shipment on hold	GUANGZHOU - CHINA MAINLAND	01:46	5 Pieces
<b>Wednesday, April 08, 2020</b>		<b>Location</b>	<b>Time</b>	<b>Pieces</b>
1	Shipment picked up	GUANGZHOU - CHINA MAINLAND	20:53	5 Pieces

If you would prefer to speak to someone personally about the location of your shipment, please

contact DHL Express Customer Service.

**Terms & Conditions**

**Tracking FAQs**

Deutsche Post DHL Group



Search the store

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## Orders

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### Orders

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Order #17679

1 product totaling \$573.85

ORDER PLACED

2020 Apr 9th

LAST UPDATE

2020 Apr 14th

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Page 1 of 1

seyitumturk@gmail.com



## DISCLAIMER

The Inevitable Hysteria Surrounding Coronavirus And COVID-19 Has Prompted The Question: Can The Face Masks You Are Buying Protect You? "We Don't Have Great Evidence In Their Effectiveness Since The Masks Don't Have A Firm Seal Around The Nose And Mouth, And People Still Breathe In Infectious Particles Around The Sides Of The Masks, Since The Coronavirus Can Be Spread Through The Air." In This Setting, Masks Help Prevent Individuals Who Are Already Sick From Spreading Their Illness To Others, But It Is Not A Substitute For Handwashing Or Social Distancing.

The Amount We Are Being Charged For The Face Masks, Sanitizer And Other Infection Control Products We Are Selling Is Much Higher Than What We Paid For Them Before The Pandemic. Therefore, The Increase In Price Is Due To The Demand For These Items During The Pandemic.



## **5. Distribution Records**

# **Distribution Records: NS**

DM	Community	Address	Contact	Date	Tracking number	Quantity			Source Supplier	
NS	We'koq'm'q First Nation	We'koq'm'aq Health Centre 93 Reservation Road We'koq'm'aq First Nation Cape Breton NS B0E3MO	Jennifer MacDonald E-mail: jennifremacdonald@waycobah.ca Phone: 9027562156	April 23, Thursday, 2020	9013233018809151	25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Wagmatcook First Nation	Wagmatcook Health Centre 47 Rear Humes Road P.O. Box 30004 Wagmatcook, NS B0E3B0	9022951844 info@wagmatcook.ca	April 23, Thursday, 2020	9013233018807157	25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Potlotek First Nation	Potlotek Health Centre 264 Sitmuk Rd St.Peter's NS B0E3B0	Laurie Touesnard E-mail: howernard@potlotek.ca Phone: 9025352961	April 23, Thursday, 2020		25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Pictou Landing	Director Of Health Pictou Landing First Nation 19 Maple St, Pictou, NS B0K 1H0	Shelley A.Young Office: 9027520085 ext.231 Cell: 9023010051 Shelley.y@pifn.ca	April 23 Thursday, 2020		25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Millbrook First Nation	Millbrook Health 812 Willow Street Truro, NS B2N 6N7	Carla Moore cmoore@millbrookhealth.ca Phone: 9028959468	April 23, Thursday, 2020		25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Sipekne'katik First Nation	601 Church Street Indian Brook NS B0N2H0	Tina Nevin Tnevin@sipeknekatik.ca Phone: 9028059990	April 23, Thursday, 2020		25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>
NS	Abegweit Wellness Centre	Director Of Health Gerard Gould 81 Gluscap Drive P.O. Box 68 Mount Stewart,PE C0A 1T0	Phone: 902676300, Cell: 9023932266	April 23, Thursday, 2020		25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq <a href="#">Dentalmarket.com</a>

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity			Source Supplier		
		Receiving Community Address					Number Of KN95 Masks	Number Of Face Shields	Number Of Nitrile Gloves	Source Supplier (KN95)	Source Supplier (Face Shields)	Source Supplier (Nitrile Gloves)
							25	25	50	Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Acadia	Marla Robinson 36 Burbine Street, Yarmouth	April 30th, 2020	2016 4270 86607186	Health Box 001	ACNS						
NS	Bear River	Bear River First Nation Health Center, 168 F	April 30th, 2020	2016 4270 8487 4184	Health Box 001	BRNS				Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Annapolis	Catherine Dubois, Annapolis Valley First Na	April 30th, 2020	2016 4270 8072 9181	Health Box 001	ANNS				Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Membertou	Darlene Anganis, Membertou Wellness Hom	April 30th, 2020	2016 4270 7728 6185	Health Box 001	MBNS	25	25	50	Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Glooscap	Glooscap First Nation Health	April 30th, 2020	2016 4270 9231 7185	Health Box 001	GCNS	25	25	50	Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Paqntkek (Antigonish)	Paqntkek Mi'kmaw Nation	April 30th, 2020	2016 4270 9087 1184	Health Box 001	ATNS	25	25	50	Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com
NS	Eskasoni	Sharon Rudderham	April 30th, 2020	2016 4270 8849 4180	Health Box 001	ESNS	25	25	100	Quanzhou Yixin Commerce&Trade Co., Ltd	Digital Mi'kmaq	Dentalmarket.com

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity	Source Supplier	INVENTORY
NS	Wagmatcook	Wagmatcook Health Center	May 7th, 2020	2016 4271 8933 8208	Health Box 002 WANS	WANS	500	0 Quanzhou Yixin Commerce&Trade Co.,Ltd	

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity			Source Supplier		
							Number Of KN95 Masks	Number Of Face Shields	Number Of Nitrile Gloves (Piece)	Source Supplier (KN95)	Source Supplier (Face Shields)	Source Supplier (Nitrile Gloves)
NS	Pictou Landing (for Oceans and Fisheries)	Receiving Community Adress  Shelley A.Young Director Of Health Pictou Landing First Nation 19 Maple St, Pictou, NS B0K 1H0	04/05/2020	2016427213791191	Health Box 002	PLFN	120	0	0	Quanzhou Yixin Commerce&Trade Co.,Ltd	-	-

# **Distribution Records: NB**

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity	Source Supplier	INVENTORY
NB	Buctouche Band	Buctouche First Nation Health Centre	May 7th, 2020	2016 4270 4469 0205	Health Box 001 BUNB	BUNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Elsipogtog First Nation	Elsipogtog Health and Wellness Centre	May 7th, 2020	2016 4270 4878 7208	Health Box 001 ELNB	ELNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Eel Ground	Eel Ground Health Centre	May 7th, 2020	2016 4270 5097 4207	Health Box 001 EGNB	EGNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Madawaska Maliseet First Nation	Madawaska Maliseet First Nation Health Centre	May 7th, 2020	2016 4270 5374 6207	Health Box 001 MMNB	MMNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Fort Folly	Fort Folly First Nation Health Centre	May 7th, 2020	2016 4270 5560 2204	Health Box 001 FFNB	FFNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Oromocto First Nation	Oromocto First Nation Wel-a-mook-took Health Centre	May 7th, 2020	2016 4270 5772 7202	Health Box 001 OFNB	OFNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Indian Island	Indian Island First Nation Health Centre	May 7th, 2020	2016 4270 6504 7200	Health Box 001 IINB	IINB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Kingsclear	Kingsclear First Nation Health and Wellness	May 7th, 2020	2016 4270 6154 5205	Health Box 001 KCNB	KCNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Pabineau	Pabineau First Nation Community Health Centre	May 7th, 2020	2016 4270 5986 5209	Health Box 001 PBNB	PBNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Esgenoopetitj First Nation	Esgenoopetitj First Nation	May 7th, 2020	2016 4270 6854 7202	Health Box 001 EFNB	EFNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	St. Mary's	St. Mary's First Nation Health Centre	May 7th, 2020	2016 4270 7121 5204	Health Box 001 SMNB	SMNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd
NB	Tobique	Tobique First Nation Neqotuk Health Centre	May 7th, 2020	2016 4270 7293 0205	Health Box 001 TFNB	TFNB	25	25	100 Quanzhou Yixin Commerce&Trade Co.,Ltd

DM	Community	Address	Contact	Date	Tracking number	Quantity		Source Supplier		
NB	Metepenagian Mi'kmaq Nation	Health Nurse Metepenagiaq First Nation 8 Shore Road Red Bank, NB, E9E 1A5	Claudette Ward Phone: 5068366100	April 23, Thursday, 2020	9013233018802152	25	25	50 Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com
NB	Eel River Bar First Nation	10 Ranch Rd Eel River Bar NB E8C3B3	Mary Lou LaBillois Phone: 5066860667	April 23, Thursday, 2020	9013233018801155	25	25	50 Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com
NB	Woodstock	Acting Health Director Executive Health Assistant/NIHB Claims Woodstock First Nation Health Centre 10 Turtle Lane	Amanda McIntosh Phone: 5063283303	April 23, Thursday, 2020	9013233018800158	25	25	50 Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com

# **Distribution Records: PEI**

DM	Community	Address	Contact	Date	Tracking number	Quantity			Source Supplier		
PEI	Lennox Island Health Centre	Director of health Michelle McLean 327 Sweetgrass Trail P.O. Box 135 Lennox Island, COB 1P0	Phone: 902 831 2711, Cell: 9024393075	April 23, Thursday, 2020		25	25		Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com

# **Distribution Records: NL**

DM	Community	Address	Contact	Date	Tracking number	Quantity			Source Supplier		
NL	Miawpukek	Conne River Health & Social Services 52 Miawpukek Dr Conne River NL A0H1J0	Margaret Ada Roberts Phone: 7098825102 crhss.com	April 23, Thursday, 2020	9013233018199153	25	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity	Source Supplier			INVENTORY
NL	Mushuau Innu First Nation	Jennifer Lister/ Kathleen Benuen	May 7th, 2020	2016 4270 7646 2207	Health Box 001 MUNL	MUNL	25	25	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com
NL	NunatuKevut	Tiffany Lamourne	May 7th, 2020	2016 4270 8609 6201	Health Box 001 NKNL	NKNL	25	25	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com

# **Distribution Records: SK**

Province	Community	Address	Date Shipped	Tracking Number	Reference Number	Client ID	Quantity			Source Supplier		
							Number Of KN95 Masks	Number Of Face Shields	Number Of Nitrile Gloves (Piece)	Source Supplier (KN95)	Source Supplier (Face Shields)	Source Supplier (Nitrile Gloves)
SK	La Loche	Teresa Florizone Suite 500 1855 Victoria Avenue Regina, SK S4P 2C6	April 24th, 2020	Unknown	Unknown	No specified yet	50	25	50	Quanzhou Yixin Commerce&Trade Co.,Ltd	Digital Mi'kmaq	Dentalmarket.com



## **6. Digital Mi'kmaq Health Guide**



DIGITAL MI'KMAQ

# PERSONAL PROTECTION EQUIPMENT GUIDE

# **Table Of Contents**

- 1. Health Canada MDEL**
- 2. KN95 Respirators**
- 3. Manufacturer & Certificates**
- 4. Safety**
- 5. How To Wear It**

# **Health Canada Compliance & Digital Mi'kmaq MDEL (Medical Device Establishment Licence)**

Digital Mi'kmaq have successfully received the MDEL licence in Class I medical device category, this allows Digital Mi'kmaq to manufacture, import and safely deliver PPE (Personal Protection Equipment) that is registered by Health Canada.

Licence Number

11778

Numéro de la licence

Medical Device  
Establishment Licence

Licence d'établissement  
pour les instruments médicaux

DIGITAL MIKMAQ

5121 SACKVILLE STREET  
SUITE 401  
HALIFAX, NOVA SCOTIA  
CANADA  
B2J 1K1

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	Yes / Oui	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made :

Attestations faites :

The establishment has documented procedures in place in respect of: <ul style="list-style-type: none"><li>• distribution records</li><li>• complaint handling</li><li>• recalls</li><li>• mandatory problem reporting</li><li>• handling, storage, delivery</li><li>• installation</li><li>• corrective action</li><li>• servicing</li></ul>	<input checked="" type="checkbox"/> [ Y ] <input type="checkbox"/> [ N ] <input type="checkbox"/> [ N ] <input type="checkbox"/> [ N ] <input type="checkbox"/> [ N ]	L'établissement a mis en oeuvre une procédure écrite concernant: <ul style="list-style-type: none"><li>• les registres de distribution</li><li>• les plaintes</li><li>• les rappels</li><li>• rapports d'incident obligatoires</li><li>• la manutention, le stockage, la livraison</li><li>• l'installation,</li><li>• les mesures correctives</li><li>• l'entretien</li></ul>
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Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2020-03-30

Minister of Health Ministre de la santé	Countersigned: Director, Medical Devices Compliance Program or delegated authority Contresigné par: Directrice, Programme de la conformité des matériels médicaux ou autorité déléguée   Anik Michelle Chartrand
--	---

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.  
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

# KN95 Respirators



**KN95** is an industry-standard and **means** that the **mask** provides the intended effectiveness of filtering 95 percent of particles with a mass median diameter of

0.3 micrometers. Therefore, the **mask** can protect you well from viruses and bacterias. Digital Mi'kmaq is importing and distributing the highest grade KN95 respirators as well as surgical gloves.

# Medical or Non-Medical, What Is The Difference ?

Digital Mi'kmaq provides **non-medical** respirators that are legally and technically eligible for medical use in Canada.



Since the COVID-19 outbreak the government and manufacturers are working together to ramp up the supply for PPE including N-95 type respirators. The name **N95** means that these respirators can filter at least %95 of air particles. KN95 is another industry name for the same type of respirator.

## A quoted paragraph from the Canadian Government's Website:

“The main difference between the **medical and non-medical** grade is that commercial N95 respirators aren't tested for fluid resistance of any type. For example, there is the ASTM test method F1862, "Resistance of Medical Face Masks to Penetration by Synthetic Blood." This test is used to determine the respirator's resistance to synthetic blood, which is directed at it under varying high pressures. The test isn't essential for use during the COVID-19 outbreak because the disease is transmitted by respiratory droplets.”

Due to high demand and low supply of PPE, the Canadian government announced that industrial (non-medical) respirators that meet standards of GB

2626-2006, GB 2626-2019, and GB 19083-2010 are also eligible for medical use during COVID-19. GB standards are specifically used to test the air filtration level of a respirator.

Our KN95 masks holds **GB 2626-2006** certification and is tested for at least %95 air filtration level.

The only major difference between non-medical and medical masks is the fluid resistance testing which can be alternated by using a face shield that is provided in the health box.

*Source link:*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html#a2>

# 3D-Printed Face Mask



**3D-printed face masks** provide a physical barrier to be used in conjunction with surgical or **KN95** respirators which provide fluid barrier and air filtration protection.

The Shield is also designed with space between the clear visor and the face to enable the user to wear other protective equipment, such as goggles in addition to **KN95** respirator masks. The pieces are easily disassembled for sterilization and reuse.

# **Manufacturer And Safety Certificates**

# Certificate of Compliance

No. 4M200407T.LGW0N08



Certificate's Holder:

Langshi Garments & Weaving Co., Ltd.  
Jinjiang

Sanou Industry Zone, Yinglin, Jinjiang, Fujian,  
362200, China

Certification ECM Mark:



Product:  
Model(s):

Protective Masks  
KN95 Protective Mask

Verification to:

Standard:  
EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

Issuance date: 07 April 2020

Expiry date: 06 April 2025

Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Bedonni





## Fiscal Year 2020

### CERTIFICATION OF REGISTRATION

This certifies that:

**Langshi Garments & Weaving Co.,Ltd.Jinjiang  
Sanou industrial zone,yinglin town,,  
Jinjiang city, Fujian, 362101, CHINA**

*Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by Shenzhen Huacetong Testing and Certification Co., ltd*

**Owner/Operator Number: 10065908**

**Device Listing#: See annex**

**Expiration Date: December. 31, 2020**

*Shenzhen Huacetong Testing and Certification Co., ltd. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. Shenzhen Huacetong Testing and Certification Co., 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 benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Shenzhen Huacetong Testing and Certification Co., 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, Shenzhen Huacetong Testing and Certification Co., ltd is not affiliated with the U.S. Food and Drug Administration.*

Executive Director

Issued: April.09, 2020

Expiration Date: Dec.31, 2020





**Fiscal Year 2020**

## **CERTIFICATION OF REGISTRATION**

**Annex to Device Listing# for Owner/Operator Number: 10065908**

<b>Proprietary Name</b>	<b>Product Codes</b>	<b>Device Class</b>	<b>Listing Number</b>	<b>Establishment Operations</b>
<i>Disposable protective masks</i>	<i>QKR</i>	<i>Not Classified</i>	<i>D386937</i>	<i>Manufacturer, Foreign Exporter</i>
<i>KN95 Protective Mask</i>	<i>MSH</i>	<i>2</i>	<i>D388088</i>	<i>Manufacturer, Foreign Exporter</i>



Executive Director

Issued: April.09, 2020

Expiration Date: Dec.31, 2020



**END OF THE ANNEX**



170011263663



170011260277



(2017)国认监认字(100)号

# 检验报告



CKTC-WT20014919-01



中国认可  
国际互认  
检测  
TESTING  
CNAS L0608

第1页 共2页

客户 提供 信息	委托单位/地址	晋江市浪仕服装织造有限公司			送样人: ---
					电话: ---
	生产单位/地址	-----			
	样品信息	样品名称:	KN95防护口罩	商标:	-----
		样品总数:	60个	颜色:	-----
	号型规格:	XL02	质量等级:	-----	
	产品款号或货号:	-----			
样品描述	1# 白色				
检验性质	委托检验	样品受理日期	2020-04-07	报告签发日期	2020-04-10
执行标准	GB 2626-2006 呼吸防护用品 自吸过滤式防颗粒物呼吸器				
检验结论	检验结果及符合性见附页。  检验单位盖章				
非标准检验方法说明	-----				
检验结果的不确定度	-----				
备注	企业要求过滤效率测试初始过滤效率，并按客供指标判定。				

批准:

单学蕙

审核:

何琳

编制:

宋晓冬





# 检验报告

CKTC-WT20014919-01

第2页 共2页

检测项目	项目描述	单位	标准值	实测值	评价	方法标准/备注
1# 白色						
呼吸阻力*	总呼气阻力	Pa	≤250	79	符合	GB 2626-2006
	总吸气阻力	Pa	≤350	127		
过滤效率	氯化钠颗粒物	%	≥95.0	初始过滤效率: 96.5	符合	GB 2626-2006
视野	下方视野	°	≥60	63	符合	GB/T 2891-1995
头带*	---	---	面罩的每条头带、带扣及其他调节部件在承受10N, 持续10s的拉力时, 不应出现滑脱或断裂	10N负荷持续10秒, 头带未出现滑脱、断裂	符合	GB 2626-2006

“\*”表示该项目不在CMA、CNAS、CAL授权范围内。

以下空白



170011263663



170011260277



(2017)国认监认字(100)号

# 检验报告



CKTC-WT20014919-02



170011263663



(2017)国认监认字(100)号

中国认可  
国际互认  
检测  
TESTING  
CNAS L0608

Page 1 of 2

Information Provided by Client	Applicant	Langshi Garments & Weaving Co., Ltd. Jinjiang Sanou Industry Zone, Yinglin, Jinjiang, Fujian, 362200, china			Contact	---
	Manufacturer	----- -----			Tel.	---
	Information of Submitted Sample	Sample Name KN95 Protective Mask Sample Count 60 Piece(s) Size XL02 Quality Grade -----			Trademark	----- ----- Colour
					Safety Category	---
		Style No. or Order No. -----				
	Test Part Description	1# White				
	Test Type	Commission Test	Date of Submission	2020-04-07	Date of Checking	2020-04-10
	Test Standards	GB 2626-2006				
	Conclusion	Test results and compliance refer to next page(s).			Stamp of Inspection Unit	
	Non-standard Check Methods	-----			Sample attached	
	Uncertainty of Result	-----				
	Remarks	As per client's request: Filtration Efficiency tested Initial Filtration Efficiency, the requirement is provided by client.				

Approver

单学蕙

Checker

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# Is It Safe To Import From China?

Yes, here is what WHO said about shipments coming from China:



World Health Organization (WHO)

February 1 ·

...

Q: Is it safe to receive a letter or a package from China?

A: Yes, it is safe. People receiving packages from China are not at risk of contracting 2019-nCoV.

From previous analysis, we know coronaviruses do not survive long on objects, such as letters or packages.

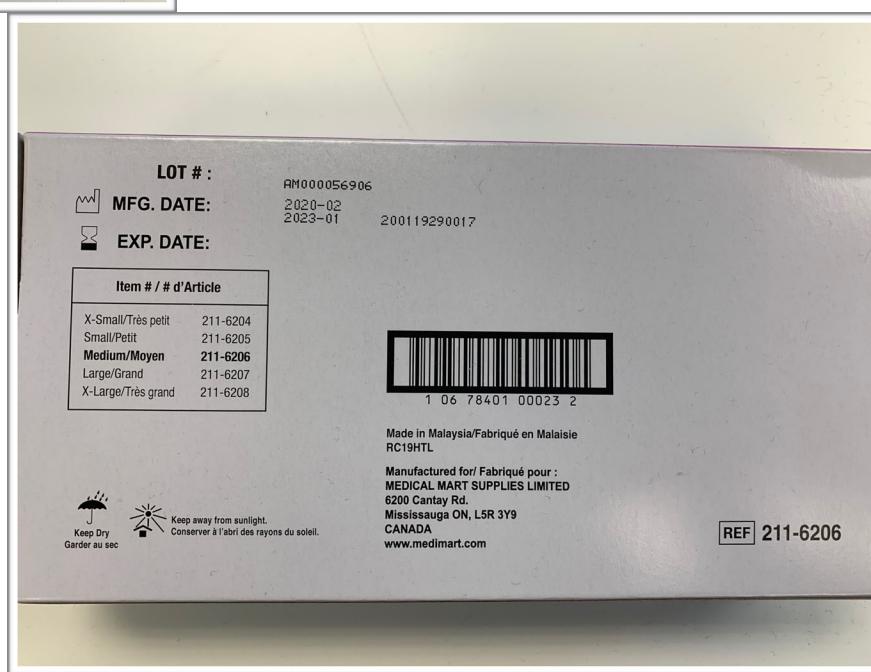
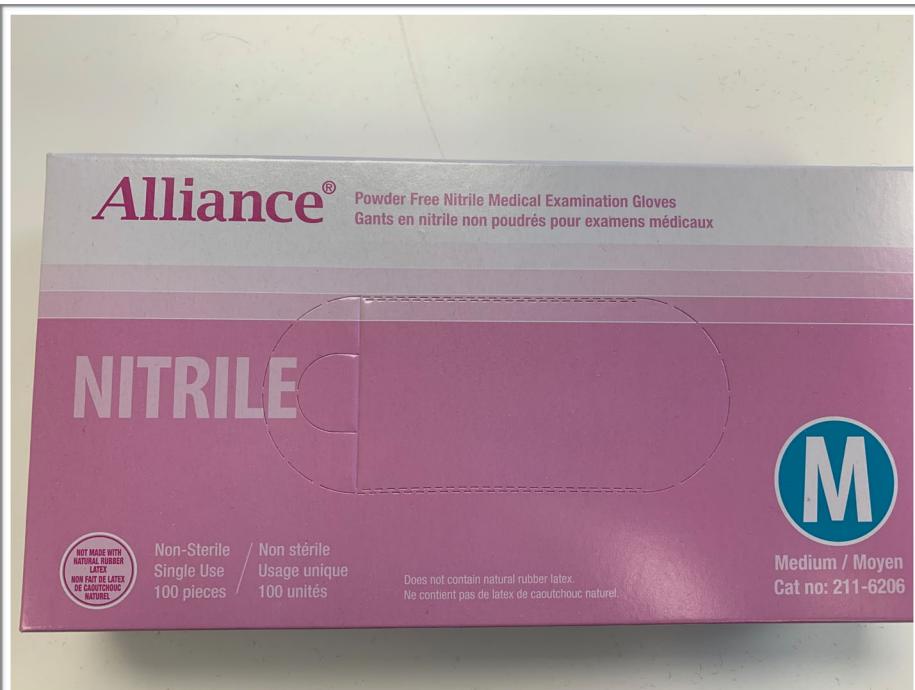
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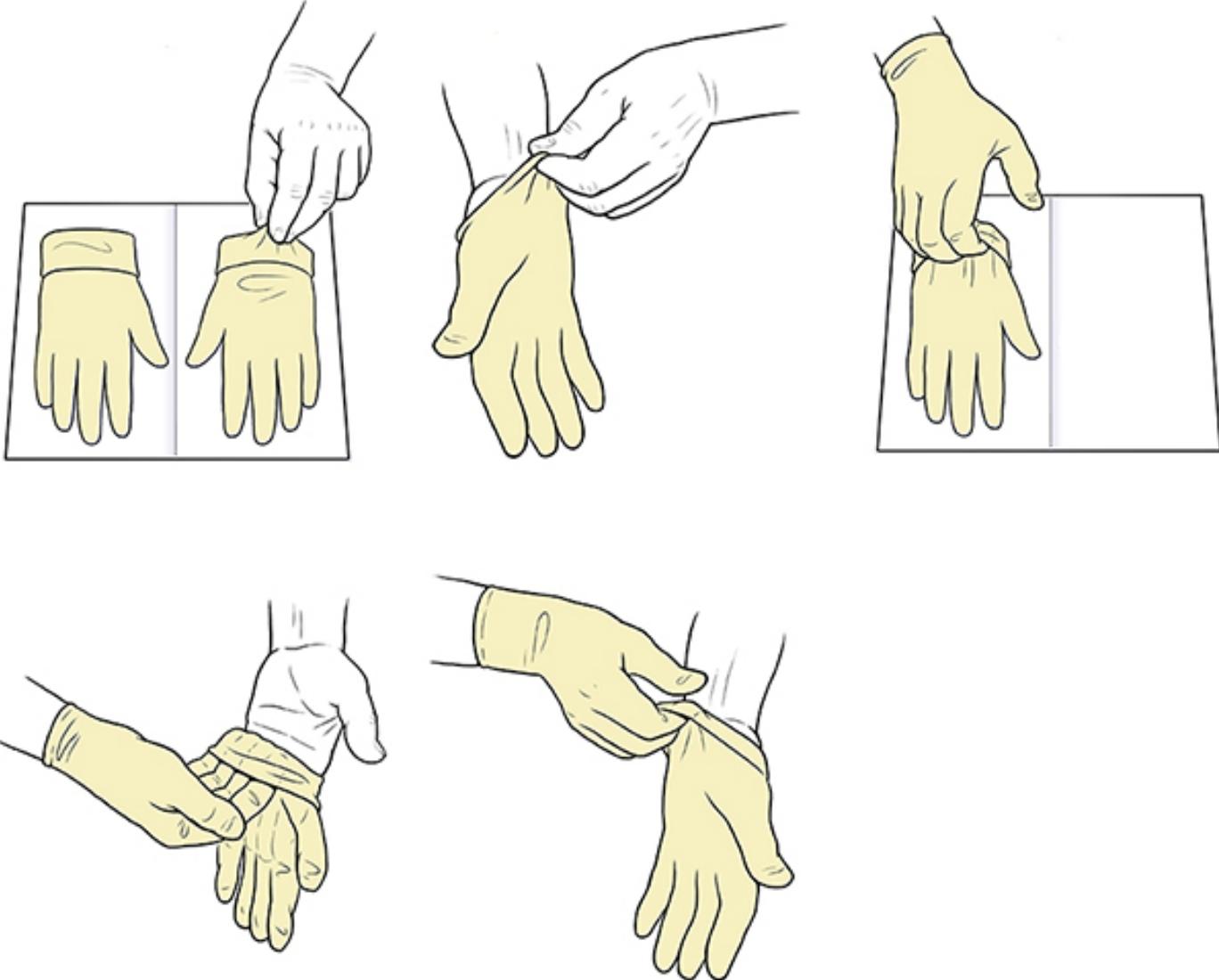
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# Surgical Gloves





## General guidelines

- Wash your hands before and after you put on a glove.
- When you handle supplies, be sure to keep them sterile and dry.
- If you are handling a packaged sterile product and not wearing gloves, only

touch the outside wrapper. Don't touch the sterile supplies when not wearing gloves.

- Don't reach over the sterile supplies while you are performing your care

# **How To Wear Your KN95 Mask And Face Shield**

# Face Masks



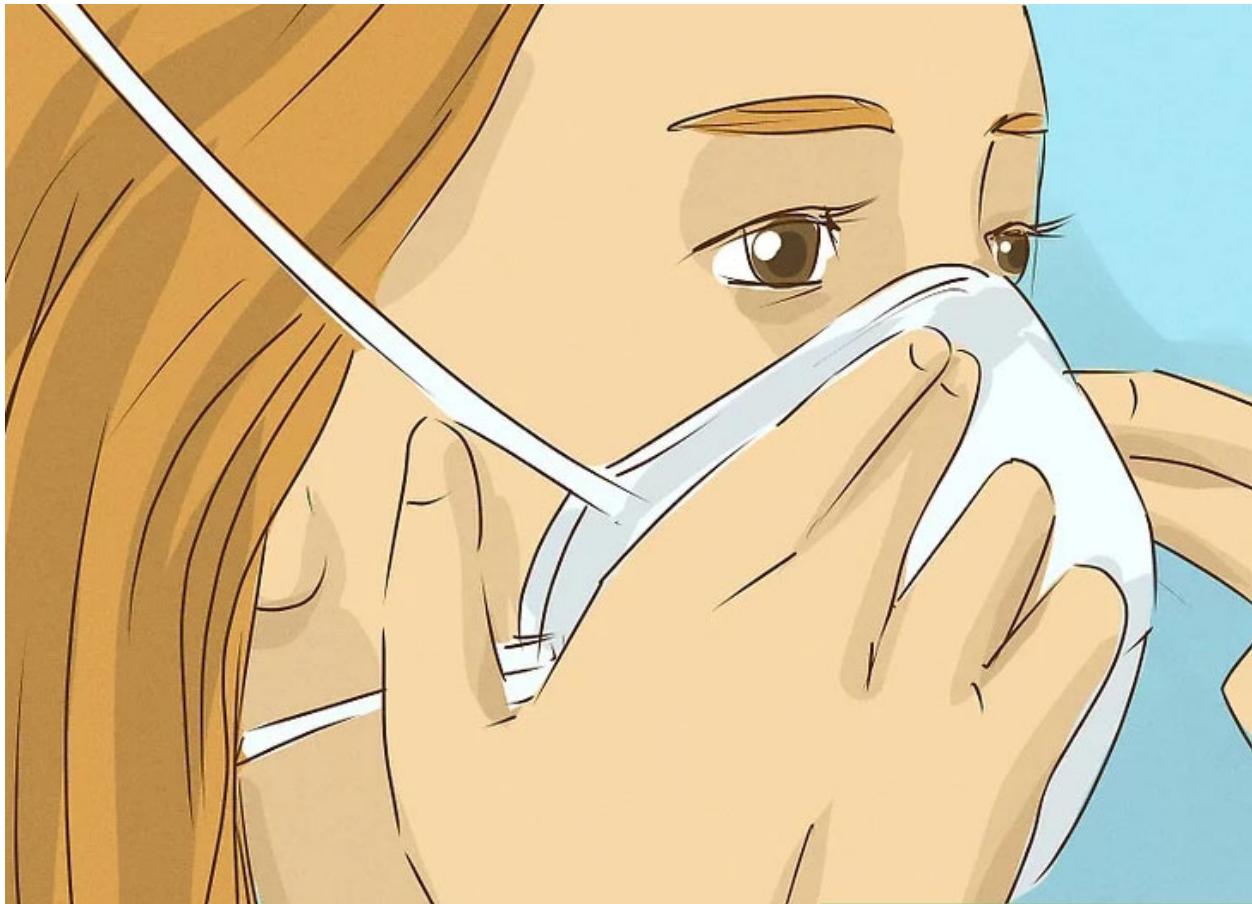
**Wash your hands well before putting on your mask.** Use soap and water and dry your hands well so you don't get the mask wet. This will prevent you from accidentally contaminating your mask before you put it on.



**Cup the mask in one hand and place it over your mouth and nose.** Place the mask in the palm of your hand so that the straps face the floor. Set it over your nose and mouth with the nosepiece fitting over the bridge of your nose. The bottom should go just under your chin. Try to touch only the outside and edges of the mask to keep it clean.

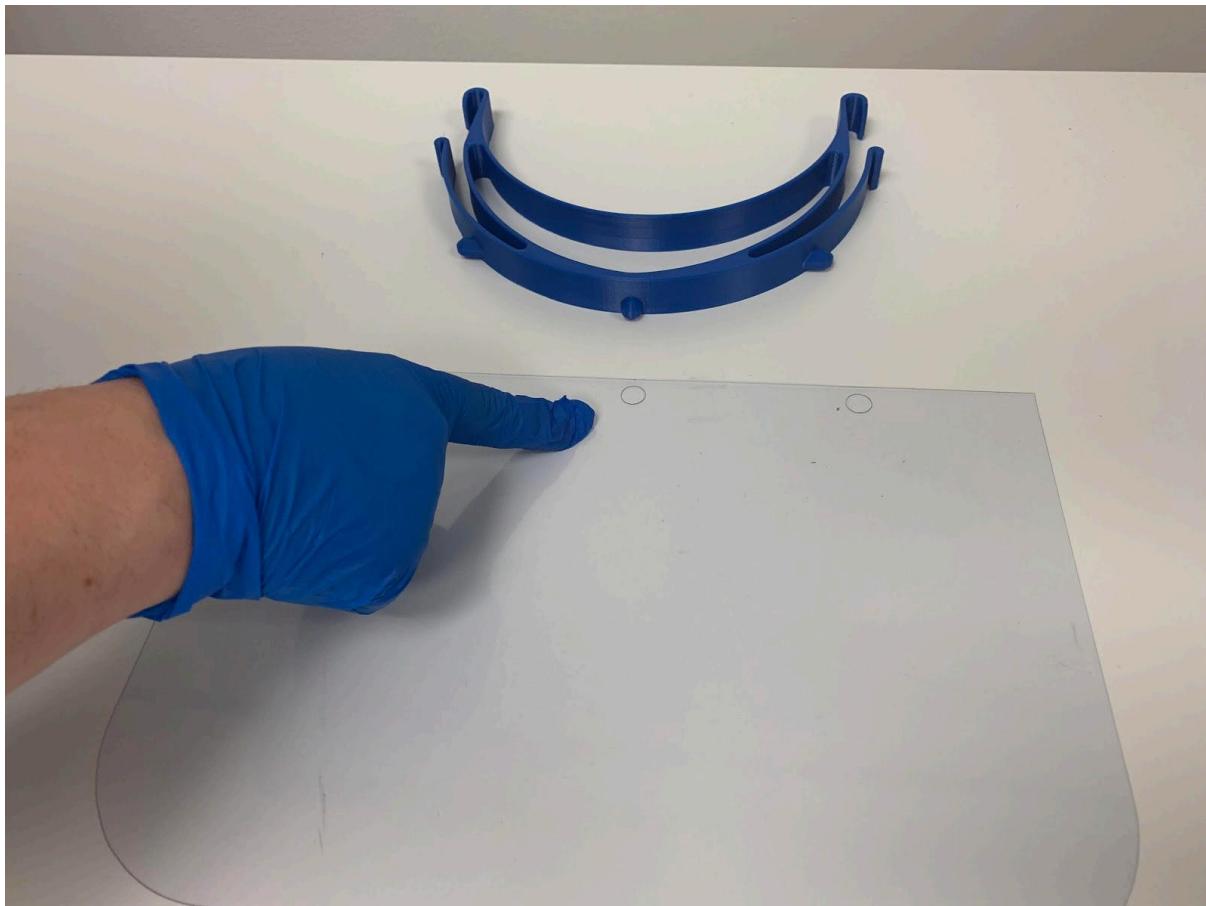


**Pull the bottom and top straps over your head.** If your mask has two straps, pull the bottom one over your head and secure it around your neck, just under your ears. Continue to hold the mask tightly against your face with the other hand. Then, pull the top strap over and set it above your ears.

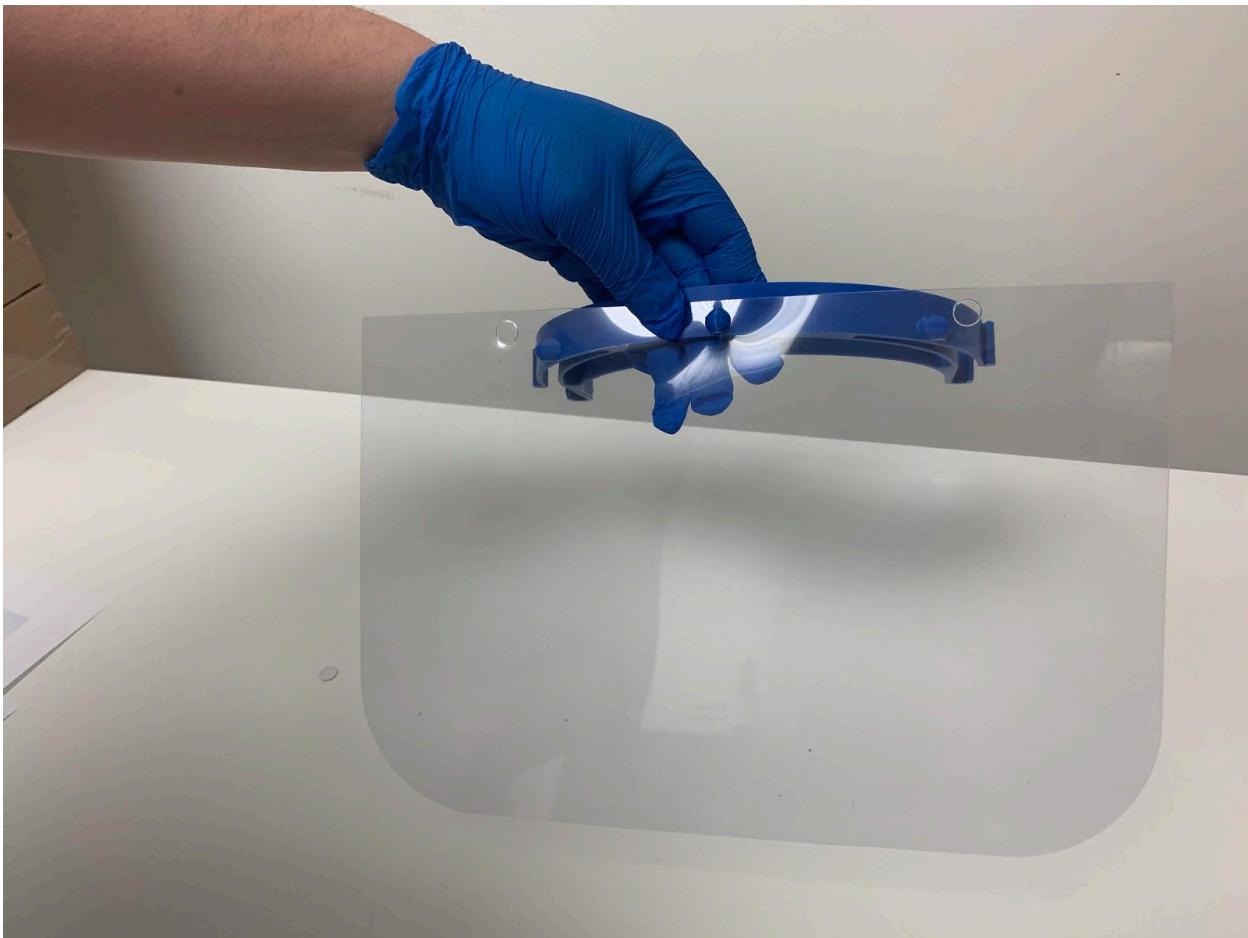


**Mold the nose piece around the bridge of your nose.** Set your first 2 finger tips on either side of the metal nose clip at the top of your mask. Run your fingers down both sides of the strip, molding it along the bridge of your nose. If your mask doesn't have a nosepiece, simply make sure the fit is tight and snug around your nose

# Face Shields



**Place the clear shield in front of you.**  
Place the headband near the top edge of the clear screen with the three holes, line them up with the three pins (protrusions). We will use them to assemble the clear shield, starting in the middle.



**Mount the clear shield on the headband,** Using the middle hole. Hold it with your thumb and forefinger, and carefully insert the pin into the corresponding clear visor slot. \*\*If the hole does not easily slide over, lubricate the pin with water or rubbing alcohol to ensure that the hole stretches over, but will still have a tight fit.



**To attach the rest of the Clear Shield;** while moving your thumb and forefinger along the band, carefully wrap the right side of the headband along the clear shield and insert the right pin. As soon as the pin is through, you can release the thumb and slide the end of the shield into the groove.

Continue on with the other side of the headband, applying the same approach. Straighten the headband slightly to stretch the final hole over the last pin, and insert the left side into the left groove. \*\*If it does not fit in the grooves, and one side is too short, simply flip the clear plastic to the other side, and begin the process again



**Attaching the elastic headband.** Take either end of the elastic band and hook it around the protrusion on the end of the headband. Place the other end of the elastic band on the opposite side of the headband. Adjust the length if needed to fit comfortably around the head.