Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **SWAB COVID-19**	Application Number/Numéro de soumission **314006**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **8083851 CANADA INC. OPERATING AS PAMA MANUFACTURING**	Company ID/Identificateur d'entreprise: **118638**
Risk Class: **2**	Rationale:
*Licence Type/Type d'homologation: **Single Device**	Rationale:
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)	
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications	

COVID-19 Medical Device & Manufacturer Details	
Class of Device	Class 1
Intended Use of Device (Section 4(1)(f))	"The intended use for this device is self-evident to the intended user, therefore an intended use statement is not necessary for which the medical device is manufactured, sold or represented, as stated in Regulation 10(h) of the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19"

Device Name	Identifier	GMDN Code	PNC Code
Swab COVID-19	SWB-0011	62723	80RYI

OEM Licence Information	
OEM Licence Name :	OEM Manufacturer :
OEM Intended Use and/or Indications for Use	

Manufacturer is requesting addition of identifier to IO. This identifier is due to a new swab they have received forcing them to create a new bill of materials for packaging.

Reason for Change		Comment(s)
Change to classification of a device	☐	
Manufacturer name change	☐	
License name change	☐	
Device name change	☐	
Change to the purpose/indication of license	☐	
Addition of device(s)	☐	
Deletion of device(s)	☐	

Reason for Change		Comment(s)
Change in name and/or address of the Private Label Manufacturer	☐	
Private Label License name change	☐	

Private Label Device name change	☐	
Addition of device(s)	☐	
Deletion of device(s)	☐	

Certificate Screening Checklist:

Cert # (new):	Cert Revisions / Comments (If Applicable):
Cert. # (old):	
Replacing Existing Cert on File (Y/N):	

Criteria	conforms	Comments/info for MDS
Issued to full name of manufacturer as it appears on application/licence and label.	☐	
Issued to complete civic address matching application/licence and label.	☐	
Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282	☐	
Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution.	☐	
Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices.	☐	
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.	☐	
Auditing Organisation is Authorized or Recognized	☐	
Statement of Authorization or Recognition.	☐	
Field labelled “Effective Date”	☐	
Field labelled “Expiry Date”	☐	
Validity period ≤ 3 years	☐	
Unique identification code labelled “certificate number” or “certification document number”	☐	☐ new ☐ revised
Name, title, and signature of certification authority	☐	
Pagination (page x or y) included on all pages . All pages present.	☐	
Method to verify validity	☐	

Screening Decision	
Accept	
Liem Whelan Device Licensing Services Division Medical Devices Bureau	**Date**: May 8th, 2020

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Check GMDN

GMDN Name	GMDN Code	GMDN Description	Issue	Action for Screener	Regulatory Action	Reference Material