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: **Class I by Non-IVDD Rule 2(2)**
*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

"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"

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

Note of approval for identifier

Liem Whelan Hey Colin, the labelling provided with the submission is deficient, no identifier
Do you want me to deficiency as per usual in this situation?

Colin Foster hmmmm
sorry for late reply
i missed your msg
identifier listed in submission not found on label
is it that we just don't have complete copy of labelling? or is it simply not there or inaccurate?

Liem Whelan I wouldn't say its inaccurate, either incomplete or not there
This manufacturer is usually very solid with indentifiers, i've done a lot of their apps

Colin Foster go ahead and move it along. you can snapshot this conversation and put it in your screening form. please follow up with the client to ensure the identifier is accurate but we will issue the IO tonight.

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)	☐	

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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**: April 20th, 2020

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Check GMDN

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