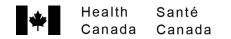


Application Information / Information de soumission					
*Licence Name/Nom de l'homologation:			Application Number/Numéro de soumission		
Swab Covid-19			314006		
Licence # / # de l'homologation:			Application Type/Type de soumission: Interim Order		
Manufacturer/Fabricant:			Company ID/Identificateur d'entreprise:		
8083851 CANADA INC. OPERATING AS PAMA MANUFACTURING			118638		
Risk Class:			Rationale:		
*Licence Type/Type d'homologation:			Class I by Non-IVDD Rule 2(2)  Rationale:		
Single Device			Rationale.		
Single Device					
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)					
*Intended Use and/or Indications for Use/ Utilisation Prévue	et/ou Indi	cations			
"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	Licanca	Information			
OEM Licence Name :	Licerice	OEM Manufac	turer :		
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)	П				
Deletion of device(s)					
Defection 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):				
Citatia		Commontolinto for NADC		
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	Date: April 20th, 2020			
Device Licensing Services Division Medical Devices Bureau				

Santé Canada Check GMDN

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