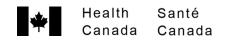


Application Information / Information de soumission								
*Licence Name/Nom de l'homologation: SWAB COVID-19					Application Number/Numéro de soumission 314006			
Licence # / # de l'homologation:						Application Ty nterim Ord	pe/Type de soumission: ler	
Manufacturer/Fabricant: 8083851 CANADA INC. OPERATING AS PAMA MANUFA				CTUI		Company ID/Io L18638	dentificateur d'entreprise:	
Risk Class:					F	Rationale:		
*Licence Type/Type d'homologation:					F	Rationale:		
Single Device	▼							
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)							iological Material(s)	
*Intended Use and/or Indications	for Use/ Utilisation Prév	ue et,	/ou Indi	catio	ns			
"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"								
	OE	M Lie	cence	Info	rmation			
OEM Licence Name :				OE	M Manufacturer	:		
OEM Intended Use and/or Indications for Use								
COVID-19 Medical Device & Manufacturer Details								
			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	•		605	GMDN Co	ode	PNC Code	
Swab COVID-19	SWB-0005 SWB-0007 SWB-0009			627	723		80RYI	
Danasa fan Chanas						C		
Change to classification of a device				Comment(s)				
Change to classification of a device Manufacturer name change								
License name change				+				
Device name change								
Change to the purpose/indication of								
license		\perp						
Addition of device(s)				\perp				
Deletion of device(s) Interim Order Amendment			Ш					
Reason for Change						Com	ment(s)	



Change in name and/or address of the	7						
Private Label Manufacturer							
Private Label License name change							
Private Label Device name change							
Addition of device(s)							
Deletion of device(s)							
Manufacturer needs to add three products (as indicated by device ide							
associated with the repackaging of devices under the PAMA Label. The ndicated in correspondence with the manufacturer. The Sterilization							
Certificate Screening Checklist:							
Cert # (new):	Cert Revisions	/ Comments (If Applicable):					
	,	,					
Cert. # (old):							
Replacing Existing Cert on File (Y/N):	_						
Replacing Existing Cert Off File (1714).							
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	\top						



Accept	•
Liem Whelan ▼	Date : April 23 rd , 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**