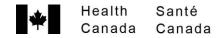
Application Information / Information de soumission						
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission					
XPERT XPRESS SARS-COV-2	312836					
Licence # / # de l'homologation:	Application Type/Type de soumission:					
0	U					
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:					
CEPHEID	114687					
Risk Class:	Rationale:					
3	IVDD Rule 2(b)(i)					
*Licence Type/Type d'homologation:	Rationale:					
Test Kit ▼						
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)						
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indic	ations					
The Xpert Xpress SARS-CoV-2 test is a rapid test intende CoV-2 in nasopharyngeal swab specimens colleted from in testing.	-					

Note: Emergency Use Authorization Request. No IO Authorization Form.

Screening Decision					
Deficient	▼				
Marie Rochefort	Date : March 23, 2020				
Device Licensing Services Division Medical Devices Bureau					

COVID-19 Medical Device & Manufacturer Details			
Class of Device	Class III		
Intended Use of Device (Section 4(1)(f))	The Xpert Xpress SARS-CoV-2 test is a rapid test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens colleted from individuals who meet CDC criteria for SARS-CoC-2 testing.		

Device Name	e Name Identifier GMDN Code		PNC Code	
XpertXpress SARS-CoV-2	XPRSARS-COV2-10	88UJH	64747	



Note to file Note au dossier

Check GMDN

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