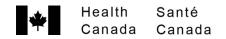


Application Information / Information de soumission				
*Licence Name/Nom de l'homologation:		plication Number/Numéro de soumission		
BIOFIRE COVID-19 TEST		314097		
Licence # / # de l'homologation:		Application Type/Type de soumission: Interim Order		
Manufacturer/Fabricant:		Company ID/Identificateur d'entreprise:		
BIOFIRE DEFENSE		151676		
Risk Class:	Ra	tionale:		
3				
*Licence Type/Type d'homologation:	Ra	tionale:		
Single Device ▼				
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)				
*Intended Use and/or Indications for Use/ Utilisation Prévue et	t/ou Indi	cations		
The BioFire® COVID-19 Test is a nested multiplex	ed real	-time RT-PCR test intended for the qualitative		
detection of nucleic acid from SARS-CoV-2 in nas				
suspected of COVID-19 by their healthcare provide	er.			
OEM Licence Information				
OEM Licence Name :		OEM Manufacturer :		
OEM Intended Use and/or Indications for Use				
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	П			
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		$\square$ new $\square$ revised		
number" or "certification document number"		□ Hew □ Fevised		
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		▼		
Emily Smalling		<b>Date</b> : Apr. 23, 2020		
Device Licensing Services Division				
Medical Devices Bureau				

Santé Canada

Check GMDN