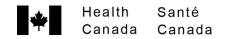
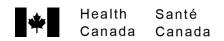


Application Informat	ion / Inf	ormation de soumission
*Licence Name/Nom de l'homologation: SOFIA 2 SARS ANTIGEN FIA		ication Number/Numéro de soumission 994
Licence # / # de l'homologation:		ication Type/Type de soumission: erim Order
Manufacturer/Fabricant: QUIDEL CORPORATION	Com	pany ID/Identificateur d'entreprise:
Risk Class:		onale: D classification rule 2(a).
*Licence Type/Type d'homologation:		onale:
Test Kit ▼		
☐ Contains Controlled Substance(s) ☐ Contains	ntains D	rug(s) Contains Biological Material(s)
*Intended Use and/or Indications for Use/ Utilisation Prévue et	/ou Indica	tions
specimens directly from individuals who are suspected of the onset of symptoms. The Sofia SARS Antigen FIA does not differentiate between Results are for the identification of SARS-CoV-2 nucleor respiratory specimens during the acute phase of infection correlation with patient history and other diagnostic information rule out bacterial infection or co-infection with other Laboratories are required to report all positive results to the Negative results should be treated as presumptive and conversely results do not rule out COVID-19 and should indecisions, including infection control decisions. Negative exposures, history and the presence of clinical signs and The Sofia SARS Antigen FIA is intended for use by train care settings, and proficient in performing tests using the The Sofia SARS Antigen FIA should be used with Sofia	reen SAR capsid produces a Positive mation is viruses. The appropriate appropr	id protein antigen from SARS-CoV-2 in nasal (NS) swab -19 by their healthcare provider within the first five days of S-CoV and SARS-CoV-2. Stein antigen. Antigen is generally detectable in upper results indicate the presence of viral antigens, but clinical necessary to determine infection status. Positive results do The agent detected may not be the definite cause of disease. So that a molecular assay if necessary for patient management. It as the sole basis for treatment or patient management thould be considered in the context of a patient's recent is consistent with COVID-19. All laboratory personnel and individuals trained in point of the Sofia 2 instruments.
OEM Intended Use and/or Indications for Use	1	
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 Davise name change		
Private Label Device name change		
Addition 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		
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		
Note this is an amendment of the name and add Decision	itionof ident	tifier - see IOR Screening
Accept		V
Roula Sifakis Vogel		Date:2020-11-04
Device Licensing Services Division Medical Devices Directorate		



Review Division – DLSD Communication	
Review Division Screener Action:	
Review Division Screener Response:	
	Date:
Review Division Screener Medical Devices Directorate	

Santé Canada

Check GMDN

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