



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: <b>SOPIA 2 SARS ANTIGEN FIA</b>	Application Number/Numéro de soumission <b>314994</b>
Licence # / # de l'homologation: <b>0</b>	Application Type/Type de soumission: <b>Interim Order</b>
Manufacturer/Fabricant: <b>QUIDEL CORPORATION</b>	Company ID/Identificateur d'entreprise: <b>108644</b>
Risk Class: <b>4</b>	Rationale: <b>IVDD classification rule 2(a).</b>
*Licence Type/Type d'homologation: <b>Test Kit</b>	Rationale:
<input type="checkbox"/> Contains Controlled Substance(s) <input type="checkbox"/> Contains Drug(s) <input type="checkbox"/> Contains Biological Material(s)	
<p>*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications</p> <p>“The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia and Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.</p> <p>The Sofia SARS Antigen FIA does not differentiate between SARS-CoV and SARS-CoV-2.</p> <p>Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories are required to report all positive results to the appropriate public health authorities.</p> <p>Negative results should be treated as presumptive and confirmed with a molecular assay if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.</p> <p>The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia and Sofia 2 instruments.</p> <p>The Sofia SARS Antigen FIA should be used with Sofia or Sofia 2.”</p>	

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	<input type="checkbox"/>	
Manufacturer name change	<input type="checkbox"/>	
License name change	<input type="checkbox"/>	
Device name change	<input type="checkbox"/>	
Change to the purpose/indication of license	<input type="checkbox"/>	
Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	

Reason for Change		Comment(s)
Change in name and/or address of the Private Label Manufacturer	<input type="checkbox"/>	
Private Label License name change	<input type="checkbox"/>	
Private Label Device name change	<input type="checkbox"/>	
Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	



**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.	<input type="checkbox"/>	
Issued to complete civic address matching application/licence and label.	<input type="checkbox"/>	
Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282	<input type="checkbox"/>	
Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution.	<input type="checkbox"/>	
Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices.	<input type="checkbox"/>	
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.	<input type="checkbox"/>	
Auditing Organisation is Authorized or Recognized	<input type="checkbox"/>	
Statement of Authorization or Recognition.	<input type="checkbox"/>	
Field labelled “Effective Date”	<input type="checkbox"/>	
Field labelled “Expiry Date”	<input type="checkbox"/>	
Validity period ≤ 3 years	<input type="checkbox"/>	
Unique identification code labelled “certificate number” or “certification document number”	<input type="checkbox"/>	<input type="checkbox"/> new <input type="checkbox"/> revised
Name, title, and signature of certification authority	<input type="checkbox"/>	
Pagination (page x or y) included on all pages . All pages present.	<input type="checkbox"/>	
Method to verify validity	<input type="checkbox"/>	

<b>Note this is an amendment of the name and addition of identifier – see IOR</b>		<b>Screening</b>
<b>Decision</b>		
<input type="text" value="Accept"/>		
<input type="text" value="Roula Sifakis Vogel"/>		<b>Date:</b> 2020-11-04
Device Licensing Services Division Medical Devices Directorate		



Review Division – DLSD Communication	
<u>Review Division Screener Action:</u>	
<u>Review Division Screener Response:</u>	
<hr/> Review Division Screener Medical Devices Directorate	Date:



Check GMDN

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