



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: SOFIA 2 SARS ANTIGEN FIA	Application Number/Numéro de soumission 314994
Licence # / # de l'homologation: 0	Application Type/Type de soumission: Interim Order
Manufacturer/Fabricant: DIAGNOSTIC HYBRIDS, INC. - ALSO TRADING AS QUIDEL CORPORATION	Company ID/Identificateur d'entreprise: 116717
Risk Class: 3	Rationale: IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation: <div style="border: 1px solid black; padding: 2px;"> Test Kit </div>	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 2 SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly or after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. S263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.</p> <p>The 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 within the United States and its territories 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 SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. The SARS Antigen FIA is only for use under the Food and Drug Administration's Emergency Use Authorization. The Sofia 2 SARS Antigen FIA is intended for use by medical professionals or trained operators who are proficient in performing tests using the Sofia 2 Instrument. The Sofia 2 SARS Antigen FIA test is only for use under the Food and Drug Administration's Emergency Use Authorization.</p>	



The Sofia 2 SARS Antigen FIA should be used with Sofia 2

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.	<input type="checkbox"/>	



devices. Does not contain product names/models/licence numbers.		
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"/>	

Screening Decision	
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> Accept ▼ </div>	
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> Gregory Jackson ▼ </div>	Date: 2020-05-12
Device Licensing Services Division Medical Devices Bureau	

Address does not match.



Health Santé
Canada Canada

Note to file
Note au dossier

Regulatory Assessment Checklist for Class I/II/III/IV IO Medical Devices Submissions

For all Class IO Medical Devices:
Section 4(1) of the Interim Order



Section of Interim Order	Requirement	A	D	N/A	Guidance	Comments
4(1)(a)	The name of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires including the name of the device. This is the name that appears on the labelling proper and for which the authorization shall be issued under the Order. It includes any information necessary for the user to identify the device and to distinguish it from similar devices.	
4(1)(b)	The class of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Specify the class of the device. This is the classification that is attributed to the device according to the rules set out in Schedule 1 of the Medical Devices Regulations. According to the classification scheme, Class I represents the lowest risk and Class IV represents the highest risk. For this purposes of submitting an application under the Interim Order, a COVID-19 medical device can be classified into more than one class, the class representing the higher risk applies.	
4(1)(c)	The identifier of device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family be provided. For greater certainty, the definitions of each of these instances have been included above (see “Definitions”).	
4(1)(d)	Name and address of the manufacturer as it appears on the device label	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4(1)(d) and 4(1)(e) requires the submission of the name and address of the manufacturer as it appears on the device label, including the address where the device is manufactured (if different). For greater certainty, this should be listed as the legal manufacturer of the device	Updated IO form
4(1)(e)	the address where the device is manufactured, if different from the one referred to in paragraph (d)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4(1)(f)	the diagnosis, treatment, mitigation or prevention for which the device is required	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires the submission include information related to the diagnosis, treatment, mitigation, or prevention for which the COVID-19 medical device be provided. This information is crucial in establishing an understanding of the device and the device classification. The following information should be included in this section: <ul style="list-style-type: none"> -intended purpose, mechanism of action, indications for use, conditions for which the device is used (the intended use statement should be verbatim as it appears on the device labelling); -patient population for which the device is intended including age range, if applicable, and specific diagnoses; - anatomical and physiological particulars related to the patient using the device, if applicable; -whether or not the device uses an energy source and whether energy is transferred to the patient; - the document version number and the date where the formal intended use appears. 	
Section of Interim Order	Requirement	A	D	N/A	Guidance	Comments



4(1)(g)	the known information in relation to the quality, safety and effectiveness of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	See Note 1 below.	
4(1)(h)	the directions for use, unless directions are not required, for the device to be used safely and effectively;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requests that the applicant provide the directions for use, unless directions are not required for the device to be used safely and effectively. This is the information supplied to the lay person and/or the health care professional enabling them to use the device without causing unnecessary harm to themselves or another person and to achieve the desired result. The Directions for Use should be written at a level commensurate with the training of the expected users. For some complex, active or powered devices, the Directions for Use may require a special Surgeon's Instruction Manual, Operator's Manual, and a User's Manual. All documents should have a control or version number clearly indicated in the document	
4(1)(i)	an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires the applicant to provide an that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls. Appendix A provides an example of what Health Canada would look for in an attestation from an applicant.	
4(1)(j)	a copy of the label of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires that the applicant provides a copy of the label of the COVID-19 medical device. This label should be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user. Additionally, where a package that contains a COVID-19 medical device is too small to display all the information required according to section 10 of the Interim Order, the directions for use shall accompany the device but need not be on the outside of the package or be visible under normal conditions for sale.	

Note 1

4(1)(g) of the Interim Order requests that the applicant provide the known information in relation to the quality, safety and effectiveness of the device. To clarify the type of information that should be submitted, the following non-exhaustive list is provided as a guide to inform a submission. The Minister, under section 9 of the Interim Order, may request any additional information, if the information provided is deemed insufficient to render a decision whether to grant an authorization under this Interim Order.

- a) A clear description of the device, including how it works, any accessories to be used with it, and diagrams/photos of the device;
- b) A copy of the manufacturer's Quality Manufacturing System Certificate, evidence of Good Manufacturing Practices, or other;
- c) A discussion of whether any components are manufactured using additive manufacturing (3D printing, laser sintering, bioprinting, etc.);
- d) If this device is manufactured from or incorporates animal or human tissue or their derivative, evidence of biological safety of the device;
- e) A summary of any mechanical/bench testing data performed for the device;
- f) A summary of any animal testing and clinical investigations carried out with the device;
- g) A summary of any biocompatibility testing performed with the device (if applicable);
- h) A summary of the evidence of shelf-life and packaging validation testing (if applicable);
- i) A summary of electrical safety and electromagnetic compatibility (EMC) testing (if applicable);
- j) If the device is intended to be used at point of care or sold directly to a consumer, marketing materials for the device;
- k) If the device is intended to be sold in a sterile condition, a description of the sterilization method and a summary of sterilization validation testing performed;
- l) A list of applicable standards used in the design/manufacture of the device;
- m) Incidents with a discussion of each event and response from the manufacturer;
- n) A comparison table outlining technological differences between this device and predecessors that are or were licensed in Canada (if applicable);
- o) A comparison table outlining technological differences between the proposed COVID-19 medical device and any available (authorized) comparators, to the applicants knowledge
- p) If the COVID-19 medical device is, or includes software, a discussion of the software validation testing performed;
- q) If the COVID-19 medical device is, or includes an in-vitro diagnostic device, analytical validation studies including but not limited to, specimen validation testing, sample preparation validation, the limit of detection, when applicable, inclusivity, cross reactivity (in silico analysis and cross reactivity testing), preliminary precision results (if applicable), stability of samples, preliminary reagent stability and clinical validity studies.



ONLY FOR CLASS III and IV IO Medical Devices:
Section 4(2) of the Interim Order

Section of Interim Order	Requirement	A	D	N/A	Guidance	Comments
4(2)(a)	a description of the materials used in the manufacture and packaging of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires that, for Class III and IV COVID-19 medical devices, the applicant provides a description of the materials used in the manufacture and packaging of the device. Additionally, if there are any materials that are patient contacting for any period of time, biocompatibility testing of those materials may be required in order to render a decision on whether the Minister may issue an authorization.	
4(2)(b)	a list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Requires that, for Class III and IV COVID-19 medical devices, the applicant provides a list of countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries. This information can be provided in any format, however, summary tables are preferred.	



Check GMDN

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