Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **BKIT VIRUS FINDER COVID-19**	Application Number/Numéro de soumission **315999**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **HYRIS LTD**	Company ID/Identificateur d'entreprise: **156034**
Risk Class: **3**	Rationale: **Classification Rule IVDD Rule 2(b)(i)**
*Licence Type/Type d'homologation: **Test Kit**	Rationale:

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

The bKIT Virus Finder COVID-19 real-time RT-PCR assay is intended for use on the bCUBE instrument for the in vitro qualitative detection of SARSCoV-2 nucleic acid in nasopharyngeal swabs (NPS) or nasal swabs (NS) specimens from patients suspected of COVID-19 disease.
The assay is meant for the detection of SARS-CoV-2 RNA, which is generally present in detectable quantity in upper respiratory specimens during the acute phase of the disease.
This test is an aid in the diagnosis of COVID-19 disease. Negative test results do not exclude SARS-CoV-2 infection and must be combined with additional data including epidemiological information, patient history and clinical observations in order to take patient management decisions.
Positive test results indicate the presence of SARS-CoV-2 RNA in the sample. Co-existence of infection from other viruses or bacterias can't be excluded.
The test outcome should be evaluated together with patient history and other clinical information in order to determine the effective infection status and to assess if that is the effective cause of the patient's disease.
In any case report all positive results to the appropriate public health authorities.
The bKIT Virus Finder COVID-19 is intended for point-of-care use by personnel specifically instructed and trained in the use of this device and of the bCUBE instrument. bKIT Virus Finder COVID-19 is a medical device purposed for a clinical trial in respect of a COVID-19 medical device, as authorized under the Interim Order Respect in Clinical Trials for Medical Devices and Drugs Relating to COVID-19 (Interim Order).

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 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 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	☐	

Screening Decision	
Accept	
Jiazhen Minnie Dai Device Licensing Services Division Medical Devices Bureau	**Date**:2020-06-11

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Check GMDN

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