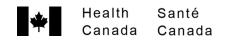


Application Information / Information de soumission						
*Licence Name/Nom de l'homologation:			Application Number/Numéro de soumission			
LYRA DIRECT SARS-COV-2 ASSAY			312783 Application Type/Type de soumission:			
Licence # / # de l'homologation: 0			Interim Order			
Manufacturer/Fabricant:			Company ID/Identificateur d'entreprise:			
DIAGNOSTIC HYBRIDS, INC ALSO TRADING AS	QUIDEL CO	DRPORATION	116717			
Risk Class:			Rationale: Classificaiton Rule IVDD Rule 2(b)(i)			
*Licence Type/Type d'homologation:			Rationale:			
Test Kit ▼						
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)						
*Intended Use and/or Indications for Use/ Utilisation Prévue	et/ou Indicat	ions				
the qualitative detection of nucleic acid from SARS-CoV-2 in nasal (NS), nasopharyngeal (NP), or oropharyngeal (OP) direct swab specimens from patients suspected of COVID-19 by their healthcare provider. The Assay targets the non-structural Polyprotein (pp1ab) of the SARS-CoV-2 virus. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 is generally detectable in upper respiratory specimens during the acute phase of infection Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The Lyra Direct SARS-CoV-2 Assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.						
OEM Licence Information						
OEM Licence Name :		EM 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)						



Deletter of the texts)			
Deletion of device(s)			
Reason for Change			Comment(s)
Change in name and/or address of the			comment(3)
Private Label Manufacturer			
Private Label License name change			
Private Label Device name change			
Addition of device(s)			
Deletion 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 app	ears		Comments/into for Wids
on application/licence and label.	curs		
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			☐ new ☐ revised
number" or "certification document number	"		
Name, title, and signature of certification			
authority			
Pagination (page x or y) included on all pages . All			
pages present.			
Method to verify validity		1 1	

Screening Decision



Accept	▼
Jiazhen Minnie Dai ▼	Date:2020-05-05
Device Licensing Services Division Medical Devices Bureau	

*
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Santé Canada

Health Canada Check GMDN

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