Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **DIASORIN SIMPLEXA COVID-19 DIRECT MOLECULAR ASSAY ON THE LIAISON MDX INSTRUMENT**	Application Number/Numéro de soumission **313264**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **DIASORIN MOLECULAR LLC**	Company ID/Identificateur d'entreprise: **107243**
Risk Class: **3**	Rationale:
*Licence Type/Type d'homologation: **Single Device**	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 DiaSorin Molecular Simplexa COVID 19 Direct real-Time RT-PCR assay is intended for use on the Liason MDX instrument for the in vitro qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) in nasopharyngeal swabs(NPS) from individuals suspected of COVID-19 by their healthcare provider. The Simplexa COVID-19 Direct assay is an aid in the diagnosis of SARS-CoV-2 infection.

OEM Licence Information	
OEM Licence Name :	OEM Manufacturer :
OEM Intended Use and/or Indications for Use	

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	
Florianne Uwera Device Licensing Services Division Medical Devices Bureau	**Date**: 2020-04-02

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Check GMDN

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