Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **LIAISON SARS-COV-2 S1/S2 IGG**	Application Number/Numéro de soumission **314838**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **DIASORIN INC.**	Company ID/Identificateur d'entreprise: **113439**
Risk Class: **3**	Rationale: **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 LIAISON SARS-CoV-2 S1/S2 IgG is a chemiluminescent immunoassay (CLIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, and plasma (sodium heparin, lithium heparin, and potassium EDTA).
The LIAISON SARS-CoV-2 S1/S2 IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist
following infection and if the presence of antibodies confers protective immunity. The LIAISON SARS-CoV-2 S1/S2 IgG should not be used to diagnose acute SARS-CoV-2 infection.The LIAISON SARS-CoV-2 S1/S2 IgG is to be used on the LIAISON XL Analyzer.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well
characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARSCoV-2 is necessary.

False positive results for LIAISON SARS-CoV-2 S1/S2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

LIASION Control SARS-CoV-2 S1/S2 IgG:
The LIAISON SARS-CoV-2 S1/S2 IgG controls (negative and positive) are intended for use as assayed quality control samples to monitor the performance of t he LIAISON SARS-CoV-2 S1/S2 IgG assay. The performance characteristics of LIAISON SARS-CoV-2 S1/S2 IgG controls have not been established for any other assays or instrument platforms.

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

Notes:
Deficiency: The manufacturer identified on the application form and documents (DiaSorin Inc., located in the US), is not identified as the manufacturer on labelling but a distributor, whereas DiaSorin S.p.A, located in Italy, is identified as the manufacturer. Need to clarify who the manufacturer is and they need adjust the labelling or application form.

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)	☐	

<u>Certificate Screening Checklist:</u>

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	
Deficient	
Jasrajbir Singh Device Licensing Services Division Medical Devices Bureau	**Date**: 2020-04-30

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Check GMDN

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