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:

- The manufacturer will relabel the packaging and it will state “manfauctured for” for the legal manufacturer (see response to [05-04-2020] request.

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	
Jasrajbir Singh Device Licensing Services Division Medical Devices Bureau	**Date**: 2020-05-12

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Check GMDN

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