

Application Information	/ Information de soumission
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission
LIAISON SARS-COV-2 S1/S2 IGG	314838
Licence # / # de l'homologation:	Application Type/Type de soumission:
0	Interim Order
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:
DIASORIN INC.	113439
Risk Class:	Rationale:
3	IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation:	Rationale:
Test Kit ▼	
Contains Controlled Substance(s)	ns Drug(s) Contains Biological Material(s)
Risk Class: 3 *Licence Type/Type d'homologation: Test Kit	Rationale: IVDD Rule 2(b)(i) Rationale: Ins 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.

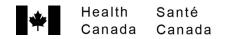
False positive results for LIAISON SARS-CoV-2 S1/S2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

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 the 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 manufacturer on labelling but a distributor, whereas DiaSorin S	S.p.A, loca		
manufacturer is and they need adjust the labelling or application	n form.		
Reason for Change			Comment(s)
Change to classification of a device	\vdash		
Manufacturer name change	Ш		
License name change			
Device name change			
Change to the purpose/indication of license			
Addition of device(s)	\vdash		
Deletion of device(s)	$\vdash \vdash$		
Deletion of device(s)	ΙШ		
Reason for Change			Comment(s)
Change in name and/or address of the			
Private Label Manufacturer	ΙШ		
Private Label License name change	П		
Private Label Device name change			
Addition of device(s)			
Deletion of device(s)			
Deletion of device(s)	_ ⊔		
Cert # (new):		Cert Revisions	/ Comments (If Applicable):
Cere ii (iiew).		cere nevisions y	comments (in 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		
on application/licence and label.			
Issued to complete civic address matching			
application/licence and label.			
Criteria are ISO 13485:2016 and Medical Dev	vices		
Regulations – Part 1 – SOR 98/282			
Scope activities limited to design, developme	ent,		
manufacture, production, servicing, installati	ion,		
or distribution.			
Activities include "manufacture" or "product	ion"		
Activities include "design" or "development a	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"	□ flew □ fevised
Name, title, and signature of certification	
authority	
Pagination (page x or y) included on all pages . All	
pages present.	
Method to verify validity	

Screening Do	ecision
Deficient	▼
Jasrajbir Singh -	Date : 2020-04-30
Device Licensing Services Division Medical Devices Bureau	

Santé Canada

Check GMDN

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