Application Information / In	formation de soumission
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission
ANTI-SARS-COV-2 IGG ELISA KIT	316823
Licence # / # de l'homologation:	Application Type/Type de soumission:
0	Interim Order
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:
DIAGNOSTICS BIOCHEM CANADA INC.	103082
Risk Class:	Rationale:
3	Classification Rule IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation:	Rationale:
Test Kit 🔻	
Contains Controlled Substance(s)	Drug(s) Contains Biological Material(s)
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indic	ations
The DBC Anti-SARS-CoV-2 IgG kit is a qu detection of IgG antibodies to SARS-CoV plasma from the adult population. The Anti-SARS-CoV-2 IgG ELISA kit is int personnel and is for laboratory use only.	-2 in human serum or K2/K3 EDTA

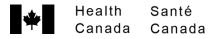
OEM Licence	Information
OEM Licence Name :	OEM Manufacturer :
OEM Intended Use and/or Indications for Use	

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)	
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 Deci	sion
Accept		
Jiazhen Minnie Dai	•	Date:2020-06-04
Device Licensing Services Division Medical Devices Bureau		



Check GMDN

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