



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: PLATELIA SARS-COV TOTAL AB	Application Number/Numéro de soumission 315786
Licence # / # de l'homologation: 0	Application Type/Type de soumission: Interim Order
Manufacturer/Fabricant: BIO-RAD	Company ID/Identificateur d'entreprise: 109132
Risk Class: 3	Rationale: Classification Rule IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation: <input type="text" value="Single Device"/>	Rationale:
<input type="checkbox"/> Contains Controlled Substance(s) <input type="checkbox"/> Contains Drug(s) <input type="checkbox"/> Contains Biological Material(s)	
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications <p>The Platelia SARS-CoV-2 Total Ab assay is an in vitro test, in a one-step antigen capture format, for the detection of IgM/IgA/IgG antibodies to SARS-CoV-2 in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.</p> <p>The assay can be used as a screening tool for the detection of anti-SARS-CoV-2 total antibodies in order to determine general population seroprevalence and/or individuals' immune status regarding exposition to SARS-CoV-2.</p> <p>Platelia SARS-CoV-2 Total Ab can be used manually or on automated systems. This test should not be used for screening of donated blood. Results from the Platelia SARS-CoV-2 Total Ab assay should not be used as the sole basis for diagnosis or for informing infection status. Canadian testing facilities are required to report all positive results to the appropriate public health authorities.</p>	

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	<input type="checkbox"/>	
Manufacturer name change	<input type="checkbox"/>	
License name change	<input type="checkbox"/>	
Device name change	<input type="checkbox"/>	
Change to the purpose/indication of license	<input type="checkbox"/>	
Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	

Reason for Change		Comment(s)
Change in name and/or address of the Private Label Manufacturer	<input type="checkbox"/>	
Private Label License name change	<input type="checkbox"/>	
Private Label Device name change	<input type="checkbox"/>	



Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	

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.	<input type="checkbox"/>	
Issued to complete civic address matching application/licence and label.	<input type="checkbox"/>	
Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282	<input type="checkbox"/>	
Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution.	<input type="checkbox"/>	
Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices.	<input type="checkbox"/>	
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.	<input type="checkbox"/>	
Auditing Organisation is Authorized or Recognized	<input type="checkbox"/>	
Statement of Authorization or Recognition.	<input type="checkbox"/>	
Field labelled “Effective Date”	<input type="checkbox"/>	
Field labelled “Expiry Date”	<input type="checkbox"/>	
Validity period ≤ 3 years	<input type="checkbox"/>	
Unique identification code labelled “certificate number” or “certification document number”	<input type="checkbox"/>	<input type="checkbox"/> new <input type="checkbox"/> revised
Name, title, and signature of certification authority	<input type="checkbox"/>	
Pagination (page x or y) included on all pages . All pages present.	<input type="checkbox"/>	
Method to verify validity	<input type="checkbox"/>	

Screening Decision	
<div style="border: 1px solid black; padding: 5px;"> Accept ▼ </div>	
<div style="border: 1px solid black; padding: 5px;"> Jiazhen Minnie Dai ▼ </div>	Date: 2020-05-15
Device Licensing Services Division Medical Devices Bureau	



Health Santé
Canada Canada

Note to file
Note au dossier



Check GMDN

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