



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: <b>BD SARS-COV-2 REAGENTS FOR BD MAX™ SYSTEM</b>	Application Number/Numéro de soumission <b>312821</b>
Licence # / # de l'homologation: <b>0</b>	Application Type/Type de soumission: <b>Interim Order</b>
Manufacturer/Fabricant: <b>BECTON DICKINSON AND COMPANY (BD)</b>	Company ID/Identificateur d'entreprise: <b>101281</b>
Risk Class: <b>3</b>	Rationale: <b>Classification Rule IVDD Rule 2(b)(i)</b>
*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><b>The BD SARS-CoV-2 Reagents for BD MAX™ System is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The BD SARS-CoV-2 Reagents for BD MAX System is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR, in vitro diagnostic procedures, and use of the BD MAX System.</b></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)
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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"/>	

<b>Screening Decision</b>
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>Accept</b> <span style="float: right;">▼</span> </div>



<b>Jiazhen Minnie Dai</b> <input type="text"/>	<b>Date:</b> 2020-06-09
Device Licensing Services Division Medical Devices Bureau	



Check GMDN

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