Арр	plication Information / Information de soumission
*Licence Name/Nom de	Application Number/Numéro de soumission
l'homologation:	318420
BD VERITOR SYSTEM FOR	
RAPID DETECTION OF SARS-	
COV-2	
Licence # / # de l'homologation:	Application Type/Type de soumission:
0	Interim Order
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:
BECTON DICKINSON AND	101281
COMPANY (BD)	
Risk Class:	Rationale:
4	COVID-19 serology-based and nucleic acidbased testing devices are Class IV
	medical devices under IVDD Classification Schedule 1, Part 2, Rule 2(a)
*Licence Type/Type d'homologation:	Rationale:
Test Kit 🔻	
Contains Controlled Substar	nce(s) Contains Drug(s) Contains Biological Material(s)
*Intended Use and/or Indications for Use	/ Utilisation Prévue et/ou Indications

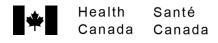
The BD Veritor System for Rapid Detection of SARS-CoV-2 is a chromatographic digital immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swabs from individualswho are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

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 De	ecision	
Accept			•
Roula Sifakis Vogel	•	Date:2020-07-29	
Device Licensing Services Division Medical Devices Directorate		-	

Review Division – DLSD Communication
Review Division Screener Action:
Review Division Screener Response:



	Date:
Review Division Screener	
Medical Devices Directorate	



Check GMDN

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