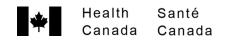


Application Inform		ation de soumission		
*Licence Name/Nom de l'homologation:		n Number/Numéro de soumission		
VTM-C19 TRANSIT TUBE		317455		
Licence # / # de l'homologation:		Application Type/Type de soumission: Interim Order		
Manufacturer/Fabricant:		Company ID/Identificateur d'entreprise:		
BIOMED DIAGNOSTICS INC	131315	,		
Risk Class:	Rationale:			
1	RULE 7(1)			
*Licence Type/Type d'homologation:	Rationale:			
Single Device ▼				
Contains Controlled Substance(s)	Contains Drug(s	s) Contains Biological Material(s)		
*Intended Use and/or Indications for Use/ Utilisation Prévu	ue et/ou Indications			
The VTM-C19 Transit Tube contains a viral medium (VTM) intended to be inoculated vinasopharyngeal (NP) or oropharyngeal (OP fiber swab specimens (Not provided, see "P section for details), transported appropriated lab and analyzed with validated qRT-PCR at the detection of the severe acute respiratory coronavirus 2 (SARS-CoV-2) that causes C disease in humans.1-2	vith P) synthetic Procedure" ly to the assays for y syndrome COVID-19	nation Manufacturer :		
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)				
הפופנוטוו טו מפאונפ(ז)				
Reason for Change		Comment(s)		
Change in name and/or address of the				
Private Label Manufacturer				
		I		
Private Label License name change				
Private Label License name change Private Label Device name change		ADDII 00 AVDIV		
Private Label Device name change		APRIL 30 AVRIL		
		APRIL 30 AVRIL 2 SESSIONAL PAPER DOCUMENT PARLEMENTAL		

Certificate Screening Checklist:

021 8550-432-1-10

HOUSE OF COMMONS **CHAMBRE DES COMMUNES**



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"		\square new \square 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	g Decision		
Accept		v	
Kevin Nguyen		Date :2020/08/17	
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	-	

*
7

Santé Canada

Health Canada Check GMDN

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