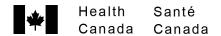


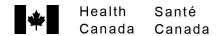
CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Application Information											
Application #: Licence Name:			ARS-COV-2 TEST					Application Type:	Device Class: 3		
Manufacturer: BIOMEME INC									Company ID: 151765		
DLSD Application Validation											
Risk Class & Rule: Licence Type 8							Application Form	Application Format:			
Class III by IVDD Rule 2(b)(i) System			▼				•	▼			
Amendment Management											
Fee Category: Reason for Amendment:											
I					<u> </u>						
1											
			Bundle	e Infor	mation	I					
Bundle Rationale: Related Appli							1 a all 6	fu Financial Powells Inf			
		▼	Bundle table	included	i?	? Create/Modify Financial Bundle Info					
Submission Completeness											
MDR		quirement			Α	D	N/A	Not	es/Comments	3	
32	Application Form										
32	Submission Presentation (ToC, Cover Letter, Exec Summary)										
32(3a/4a)	Device Description (as it relates to device listing in form)										
32(3j/4p)	QMS Certificate MDSAP/CSA- ISO 13485:2016										
32(3g/4o) Labelling – 21(1a)(1b)(1c)											
DLSD Recommendation											
Incomple											
Notes/Comments: New request form and IFU provided in COMMUNICATION INTERNAL [2020-03-27]. The IFU still disclaims that the test is for research use only and that it is not for human or veterinary diagnostics.											
Steven McClelland Bureau of Licensing Services Medical Devices Directorate								Date: March 27, 2020			
Review Division – DLSD Communication											
Review Division Screener Action:											
Review Division Screener	Res	sponse:									
									Date:		
Review Division Screener Medical Devices Directorate				-							



CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Technical Screening (Review Division)						
Proposed reviewer:			Estimated Review Time (days):	Review Complexity:		
		┰		▼		
Review Components Review Required Defi			Comments			
		s III + IV				
General Application Organization						
Device Description						
Marketing History						
Standards & Conformity Declaration						
Analytical Performance						
Physical & Chemical Bench Testing						
Electrical & Radiation Safety						
Software Validation & Verification						
Biocompatibility & Pyrogenicity	E	E				
	E.S.	East Final				
Sterilization, Packaging, &Shelf Life Animal Testing		La.				
Stability						
Product Stability (Shelf Life)	E21					
Usability	E.S.					
Clinical Studies	E	E.				
Bibliography						
Near patient IVDD	E					
Labelling						
Labouring	Clas	ss IV				
Risk Assessment	Clas	33 1				
Quality Plan						
Biological Safety						
Manufacturing Process						
Process Validation						
Note to the Reviewer (e.g. predicate, reference SBD?	nce, cautio	ns, direc	ctions)	Review incl.		
Recommendation						
Trecommendation				•		
Bundle Update/Modification - To DLS manage	er 🗆					
Technical Screening Deficiencies:						
1.						
		<u> </u>				
						



CONSOLIDATED SCREENING FORM MEDICAL DEVICES

DLSD Deficiencies					
Over Paid Fee Deficiency					
diagnostics" suggests that Biomeme SARS-CoV-2 G as a COVID-19 medical de If you can confirm this is in and sale of a COVID-19 m intended use of this device accordingly and resubmit f	to the interpretation of a device in the <u>Food and Drugs Act</u> and a medical				
 Pursuant to Section 10 of the a. The control number b. The expiry date of th 	Interim Order, please provide labelling that also displays the following: e device				
Certificate Screening Checklis ☐ MDSAP ☐ Ce	ertificate Previously Validated				
Cert # (new):	Cert Revisions / Comments (If Applicable):				
Cert. # (old):					
Replacing Existing Cert on File (Y/N):					