Health Canada / Santé Canada

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Application Information

Application #:	Licence Name:	Application Type:	Device Class:
312839 Licence #: **0**	**BIOMEME SARS-COV-2 TEST**		**3**
Manufacturer: **BIOMEME INC**		Company ID: **151765**	

DLSD Application Validation

Risk Class & Rule:	Licence Type & Rationale:	Special Substances:	Application Format:
Class III by IVDD Rule 2(b)(i)	**System**		

Amendment Management

Fee Category:	Reason for Amendment:

Bundle Information

Bundle Rationale:	Related Applications Bundle table included?	Create/Modify Financial Bundle Info
	☐	

Submission Completeness

MDR	Requirement	A	D	N/A	Notes/Comments
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 Response:

Review Division Screener
Medical Devices Directorate

Date:

Health Canada Santé Canada

CONSOLIDATED SCREENING FORM
MEDICAL DEVICES

Technical Screening (Review Division)

Proposed reviewer:	Estimated Review Time (days):	Review Complexity:

Review Components	Review Required	Deficient	Comments
Class 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	☐	☐	
Sterilization, Packaging, &Shelf Life	☐	☐	
Animal Testing	☐	☐	
Stability	☐	☐	
Product Stability (Shelf Life)	☐	☐	
Usability	☐	☐	
Clinical Studies	☐	☐	
Bibliography	☐	☐	
Near patient IVDD	☐	☐	
Labelling	☐	☐	
Class IV			
Risk Assessment	☐	☐	
Quality Plan	☐	☐	
Biological Safety	☐	☐	
Manufacturing Process	☐	☐	
Process Validation	☐	☐	

Note to the Reviewer (e.g. predicate, reference, cautions, directions) ☐ Foreign Review incl. ☐ SBD?

Recommendation

Bundle Update/Modification – **To DLS manager** ☐

Technical Screening Deficiencies:

1.

DLSD Deficiencies	
☐ **Over Paid Fee Deficiency**	

1. The disclaimer in the user manual stating "**For Research Use Only.** Not for use in human veterinary diagnostics" suggests that the Franklin Real-Time PCR Thermocycler and Biomeme Go App, Biomeme SARS-CoV-2 Go Strips, and M1 Sample Prep Cartridge Kit for RNA 2.0 do not qualify as a COVID-19 medical devices as they are not intended to be used in COVID screening/diagnosis. If you can confirm this is indeed accurate then we will not proceed with the authorization for import and sale of a COVID-19 medical device. Or, if the current labelling does not accurately reflect the intended use of this device in the context of the COVID-19 pandemic, please modify the labelling accordingly and resubmit for assessment.

   In this case, you may refer to the interpretation of a device in the *Food and Drugs Act* and a medical device in the *Medical Devices Regulations*.

2. Pursuant to Section 10 of the *Interim Order*, please provide labelling that also displays the following:
   a. The control number
   b. The expiry date of the device

Certificate Screening Checklist:

☐ MDSAP ☐ Certificate Previously Validated

Cert # (new):	Cert Revisions / Comments (If Applicable):
Cert. # (old):	
Replacing Existing Cert on File (Y/N):	