Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **BIOMEME SARS-COV-2 TEST**	Application Number/Numéro de soumission **312839**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **BIOMEME INC**	Company ID/Identificateur d'entreprise: **151765**
Risk Class: **4**	Rationale: **IVDD Rule 2(a)**
*Licence Type/Type d'homologation: **Test Kit**	Rationale:

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

Biomeme's SARS-CoV-2 Test is a multiplex assay intended for qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal and oropharyngeal (throat) swab samples. The test utilizes Biomeme's M1 Sample Prep Cartridge for RNA extraction, Biomeme's SARS-CoV-2 Go-Strips assay, and Biomeme's portable Franklin Real-Time qPCR Thermocycler. Franklin's companion mobile app, Biomem Go, scans tests, runs your PCR experiments online or offline, and is used to quickly interpret your test results while conveniently syncing your data to the Biomeme Cloud.

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:

Health Canada / Santé Canada

Note to file
Note au dossier

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

Note to reviewer: The amendment includes the additional information requested within one month as outlined in the IO Authorization issued 2020-06-29:

1. Site to site study
2. Cross-reactivity study

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 Decision	
Accept	
Mohammad Jamal Device Licensing Services Division Medical Devices Directorate	**Date**: 2020-08-20

Review Division – DLSD Communication

Health Canada Santé Canada

Note to file
Note au dossier

Review Division Screener Action: Review Division Screener Response:	
_____ Review Division Screener Medical Devices Directorate	Date:

Health Canada Santé Canada

Note to file
Note au dossier

Check GMDN

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