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 GO-STRIPS**		**2**
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

Rejection Rationale:

Notes/Comments:
Labelling currently has the disclaimer “For Research Use Only. Not for use in human or veterinary diagnostics.” Therefore, labelling suggests this may not be a medical device.

Steven McClelland
Bureau of Licensing Services
Medical Devices Directorate

Date:
March 25, 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** ☐

Rejection Rationale:

Technical Screening Deficiencies:

1. _____

_____ _____

DLSD Deficiencies

☐ **Over Paid Fee Deficiency**

1. Defined in the *Food and Drugs Act*, a device is an instrument apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in
    a. Diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
    b. Restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
    c. Diagnosing pregnancy in human beings or animals,
    d. Caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
    e. Preventing conception in human beings or animals,

    However, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

    In accordance to the *Medical Devices Regulations* and in respect, the *Interim Order*, a medical device is defined as a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

    Currently, the labelling provided sets out the following disclaimer:
    For Research Use Only. Not for use in human or veterinary diagnostics.

    Thus, the items proposed in the submission do not meet the definition of a COVID-19 medical device and cannot receive authorization for importation or sale in Canada through this regulatory pathway.

2. Pursuant to Section 4(1)(g) of the *Interim Order*, an application for the authorization of importation or sale of a COVID-19 medical device must contain sufficient information and material to enable the Minister to determine whether to issue the authorization and must include the known information in relation to the quality, safety and effectiveness of the device.

3. Pursuant to Section (4)(2) of the *Interim Order*, an application in respect of a Class III or IV COVID-19 medical device must contain, in addition to the information and material referred to in subsection (1), the following:
    a. A description of the materials used in the manufacture and packaging of the device; and
    b. A list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries.

    ***Note: Pursuant to Section 4(3), despite subsection (1) and, if applicable, subsection (2), the application need not include the information and material referred to in paragraph (1)(g) and, if applicable, paragraphs (2)(a) and (2)(b) if the applicant provides information that demonstrates that the sale of the COVID-19 medical device is authorized by a foreign regulatory authority and has not been suspended.**

4. Pursuant to Section 10 of the *Interim Order*, please provide labelling that also displays the following:

a. The name and address of the manufacturer
b. The identifier of the device
c. The control number
d. The expiry date of the device

5. The submission suggest that the device also consists of a component in the form of a mobile app. Please provide the name, identifier and labelling for this device. Note that images displayed on the screen of a software device is recognized as labelling.

Certificate Screening Checklist:

☐ MDSAP ☐ Certificate Previously Validated

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

Criteria	Conforms	Comments/info for MDS
First (most prominent) and full name on cert. matches application/licence, and label.	☐	
Address on cert. matches application, licence, and label.	☐	
Standard is (CAN/CSA) ISO 13485:2003 or 2016.	☐	
Scope includes “manufacture” or “production”. Scope includes “design” (fr. Conception) for Class III-IV.	☐	
Scope is unambiguous and covers app. device. Scope does not contain specific product names / models / numbers or licence numbers. Reference to attachment is acceptable.	☐	
Registrar is recognized.	☐	
SCC logo and CMDCAS references are present.	☐	
Effective date of registration. Field is identified as **“Effective Date”**	☐	
Expiry date. Field is identified as **“Expiry”**, **“Expiry Date”**, or **“Recertification Due Date”**	☐	
Validity period ≤ 3 years.	☐	
Certificate contains Unique Certificate Number.	☐	
Name, title, and signature of certification authority.	☐	
All pages of certificate are present.	☐	

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 13485:2003 or 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	☐	

ISO 13485 Quality Management System Certificate Screening	
Cert. # (new):	Cert. # (old) :
Cert revisions:	
First (most prominent) and full name on cert. matches application/licence, and label.	Effective date of registration. Field is identified as “Effective Date”
Address on cert, matches application, licence, and label.	Expiry date. Field is identified as “Expiry” or “Expiry date”. Or “Recertification due date”.
Standard is (CAN/CSA) ISO 13485:2003 or 2016	Validity period <= 3 years.
Scope includes “manufacture” or “production”. Scope includes “design” (fr. conception) for Class III-IV.	Certificate contains unique certificate #. New Revised
Scope is unambiguous and covers app. device. Scope does not contain specific product names / models / numbers or licence numbers. Reference to attachment is acceptable.	Name, title, and signature of certification authority.
Registrar is recognized.	Number of additional sites appearing on certificate:
SCC logo CMDCAS reference are present.	All pages of certificate are present.