

Review Division Screener Response:

Review Division Screener Medical Devices Directorate

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

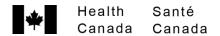
Application Information								
Application #: Licence Name:							pplication	Device
312839					'	ype:	Class:	
Licence #: 2								
Manufacturer:						company ID:		
BIOMEME INC 151765								
		ication Valida						
Risk Class & Rule:	Licence Type & Rationale:	Special Substances:			Appl	ication Form	at:	
Class III by IVDD Rule 2(b)(i)	System	<u> </u>			₹			
Amendment Management								
Fee Category: Reason for Amendment:								
				▼				
	▼	1						
	Bundi	e Information						
Bundle Rationale:	Related App	olications						
	Bundle table			Create/Modify Financial Bundle Info				
,								
	Submissi	on Completenes	SS				l	
MDR Requirement				Α	D	N/A	Notes/C	omments
32 Application For	n			~				
32 Submission Pre	sentation (ToC, Cover Le	ttor Evon Summ	on()			~		
	tion (as it relates to device		ary)	-				
	MDSAP/CSA-ISO 13485					~		
32(3g/4o) Labelling – 21(7.2010						
22(0g/ 10) 2aboming 21((10)(10)			Ш	~			
	DLSD R	ecommendation	1	•				
Incomple							-	-
Rejection Rationale:								
Notes/Comments:								
Labelling currently has the			for us	e in h	numan	or ve	terinary d	iagnostics."
Therefore, labelling suggests this may not be a medical device.								
					Date:			
Steven McClelland							March	25, 2020
Bureau of Licensing Services Medical Devices Directorate					•			
Review Division – DLSD Communication								
Review Division Screener A								

JUNE 11 JUIN 2021 SESSIONAL PAPER

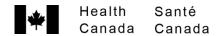
8550-432-1-15
HOUSE OF COMMONS

CHAMBRE DES COMMUNES

Date:



Technica	<mark>l Screeni</mark> n	<mark>ig (Revi</mark>	ew Division)		
Proposed reviewer:			Estimated Review Time (days):	Review Complexity:	
				_	
eview Components Review Required Deficient		Deficient	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					
Sterilization, Packaging, &Shelf Life					
Animal Testing					
Stability					
Product Stability (Shelf Life)					
Usability					
Clinical Studies					
Bibliography					
Near patient IVDD					
Labelling					
	Cla	ss IV			
Risk Assessment					
Quality Plan					
Biological Safety					
Manufacturing Process					
Process Validation					
Note to the Reviewer (e.g. predicate, reference SBD?	nce, cautio	ons, direc	ctions)	Review incl.	
Recommendation					
				Ţ	
]	_				
Bundle Update/Modification – To DLS manage	er				
Rejection Rationale:					
Technical Screening Deficiencies:					
1.					





	DLSD Deficiencies
☐ Over Paid Fee Deficiency	

- 1. Defined in the <u>Food and Drugs Act</u>, 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 <u>Medical Devices Regulations</u> and in respect, the <u>Interim Order</u>, 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 <u>Interim Order</u>, 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 <u>Interim Order</u>, 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

on application/licence and label.

- 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 Previous	ly 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		



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		☐ new ☐ revised	
number" or "certification document number"		I liew I 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 Manageme	ent System (Certificate Screening	
Cert. # (new):		Cert. # (old):	
Cert revisions:			
First (most prominent) and full name on cert. matches		Effective date of registration. Field is identified	
application/licence, and label.	as "Effective Date"		
Address on cert, matches application, licence, and label.		as "Effective Date"	
		Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date".	
Standard is (CAN/CSA) ISO 13485:2003 or 2016		Expiry date. Field is identified as "Expiry" or	
Standard is (CAN/CSA) ISO 13485:2003 or 2016 Scope includes "manufacture" or "production". Scope includes (fr. conception) for Class III-IV.	s "design"	Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date".	
Scope includes "manufacture" or "production". Scope includes	ntain specific	Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date". Validity period <= 3 years. Certificate contains unique certificate #.	
Scope includes "manufacture" or "production". Scope includes (fr. conception) for Class III-IV. Scope is unambiguous and covers app. device. Scope does not coproduct names / models / numbers or licence numbers. Reference to attachmen	ntain specific	Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date". Validity period <= 3 years. Certificate contains unique certificate #. New Revised Name, title, and signature of certification	

