Health Canada / Santé Canada

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Application Information

Application #:	Licence Name:	Application Type:	Device Class:
312912 Licence #: **0**	**REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING 2019-NCOV**		**3**
Manufacturer: **BGI GENOMICS CO., LTD**		Company ID: **151820**	

DLSD Application Validation

Risk Class & Rule:	Licence Type & Rationale:	Special Substances:
IVDD Rule 2b(i)	**TEST KIT**	

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

Complete

Reject Rationale:

Notes/Comments:

M. ROCHEFORT

Device Licensing Services Division
Medical Devices Bureau

Date:
May 4, 2020

Review Division – DLSD Communication

Review Division Screener Action:

Review Division Screener Response:

Review Division Screener
Medical Devices Bureau

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.

2020-05-04

[ENTER YOUR NAME]
Manager, [ENTER YOUR DIVISION]

DLSD Deficiencies	
Over Paid Fee Deficiency	**Class 3 -- Payment $0 By N/A**
1.	

Certificate Screening Checklist:

☐ MDSAP ☐ CMDCAS ☐ 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.	☐	

CONSOLIDATED SCREENING FORM
MEDICAL DEVICES

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.