Health Canada / Santé Canada

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

Application Information

Application #:	Licence Name:	Application Type:	Device Class:
312757 Licence #: **0**	**GENEFINDER COVID-19 PLUS REALAMP KIT**		**3**
Manufacturer: **OSANG HEALTHCARE CO., LTD.**		Company ID: **131655**	

DLSD Application Validation

Risk Class & Rule:	Licence Type & Rationale:	Special Substances:	Application Format:
Class III by IVDD Rule 2(b)	**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)	☐	☑	☐	Manufacturer's name and address is not on the label.

DLSD Recommendation

Incomple

Rejection Rationale:

Notes/Comments:
Application states the test kit is compatible with the Applied Biosystems 7500/7500Fast by Thermo Fisher and the CFX96 Real-time PCR Instrument System by Bio-Rad, but licence numbers were not provided. Thus, regulatory status of these devices are not immediately clear. Device risk class and rationale was not provided, but the risk classification rules for IVDD suggest that the device is Class III by Rule 2(b)(i).

Steven McClelland Bureau of Licensing Services Medical Devices Directorate	Date: March 19, 2020

Review Division – DLSD Communication

Review Division Screener Action:

Review Division Screener Response:

	Date:

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Review Division Screener Medical Devices Directorate	

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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.

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DLSD Deficiencies	
☐ **Over Paid Fee Deficiency**	

1. Pursuant to Section 10(b) of the *Interim Order*, a person must not import or sell a COVID-19 medical device unless the device has a label that sets out the name and address of the manufacturer. Please submit labelling of the device that includes the name and address of the manufacturer.
2. Pursuant to Section 4(1)(i) of the *Interim Order*, an application for the authorization of importation or sale of a COVID-19 medical device must include an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls. Please provide an attestation as it was not included in the initial submission.
3. Pursuant to Section 4(2)(a) 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), a description of the materials used in the manufacture and packaging of the device. Please provide this information as it was not included with the initial submission.
4. Pursuant to Section 4(2)(b) 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), 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. The FAQ provided states that the device is being sold in South Korea, France, and Italy, but the number of units sold is not indicated. Please provide this information.

Certificate Screening Checklist:

☐ MDSAP ☐ Certificate Previously Validated

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

COVID-19 Medical Device & Manufacturer Details	
Class of Device	Class III
Intended Use of Device (Section 4(1)(f))	COVID-19 Kit is the One-Step Reverse Transcription Real-Time PCR Kit designed to detect Novel Corona virus (COVID-19) qualitatively through Reverse Transcription reaction and Real-Time Polymerase Chain Reaction.

Device Name	Identifier	GMDN Code	PNC Code
GeneFinder COVID-19 Plus RealAmp Kit	IFMR-45	60090	88UJH

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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.