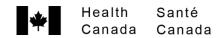
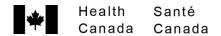


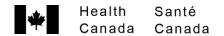
Application Information										
Application #:		Licence Name:	Applicati	OII II	IIOIII	iauc	ווע		Application	Device
312757 GENEFINDER COVID-19 PLU			IIS REALAMP KIT			Type:	Class:			
Licence #:										3
0										
Manufacturer OSANG H	: EALTHCARE CO	., LTD.							Company ID: 131655	
		וח	SD Appli	catio	n Va	alida	tion			
Risk Class &	Rule:	Licence Type &			al Subs				Application Form	at·
	/DD Rule 2(b)	Test Kit	rationalo.	Special Substances.				-	/ tppiloditori i om	₩
			Amendme	ent Ma	anage	men	t		,	
Fee Category	:			Reaso	on for A	mendi	ment:			
			Ţ							-
			Bundl	e Info	rmati	on				
Bundle Ration	nale:		Related Appl	ications	5					
		▼	Bundle table					Create/Modify	Financial Bundle	Info
			Submission	n Co	mplet	enes	S			
MDR	Requirement				Α	D	N/A	Notes/Com	nments	
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)				~		Manufactur	er's name and	d address	
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 Date: March 10, 2020										
Bureau of Licensing Services Medical Devices Directorate March 19, 2020										
Review Division – DLSD Communication										
Review Division Screener Action:										
Review Division Screener Response:										
Data										
								Date:		

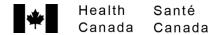


Review Division Screener
Medical Devices Directorate



Technical Screening (Review Division)					
Proposed reviewer:			Estimated Review Time (days):	Review Complexity:	
		▼			
Review Components Review Required Deficien			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					
	Clas	ss 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					
Teconimendation					
Bundle Update/Modification – To DLS manager					
Rejection Rationale:					
Technical Screening Deficiencies:					
1.					



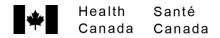


Replacing Existing Cert on File (Y/N):

DLSD Deficiencies							
Over Paid Fee Deficiency							
V							
		eder, a person must not import or sell a COVID-19					
		nat sets out the name and address of the manufacturer.					
_		udes the name and address of the manufacturer.					
* *		er, an application for the authorization of importation					
		nclude an attestation by the applicant that documented					
		on records, complaint handling, incident reporting and					
		not included in the initial submission.					
		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						
` '		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 <i>Interim Order</i> , an application in respect of a Class III or IV						
	,	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 # (new):		Cert Revisions / Comments (If Applicable):					

COVID-19 Medical Device & Manufacturer Details			
Class of Device	Class III		
Intended Use of Device (Section	COVID-19 Kit is the One-Step Reverse Transcription		
4(1)(f)) 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-	IFMR-45	60090	88UJH
19 Plus RealAmp Kit			



Criteria	Conforms	Comments/info for MDS
First (most prominent) and full name on cert.		
matches application/licence, and label.	<u> </u>	
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.		
	1	1



□ new	☐ revised
]

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.			