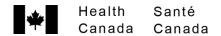


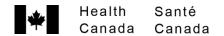
Review Division Screener Medical Devices Directorate

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

DLSD Application Validation										
		Licence Type 8	Rationale:	Special Substances:		Appl		olication Format:		
Class III by IV	VDD Ruie 2(b)(i)	Test Kit								
Amendment Management										
Fee Category	Fee Category:  Reason for Amendment:									
							Ţ			
	<b>▼</b>									
			Dundl	e Information						
Dundle Detion	a a la c									
Bundle Rationale: Related Applications			Create/Modify Financial Bundle Info							
			Bundle table	included?				•		
			Submission	on Completene	ss					
MDR	Requirement					Α	D	N/A	Notes/Comm	ents
32	Application Form	n						<u>&lt;</u>		
00							~			
32	Submission Pres				ary)	+-		~		
32(3a/4a) 32(3j/4p)	Device Descripti  QMS Certificate					+-		~		
32(3g/4o)			-130 13463	.2010		+				
02(09/10)	32(3g/4o) Labelling – 21(1a)(1b)(1c)									
			DLSD Re	ecommendation	1					
	Complete								•	
Rejection Rationale:										
Notes/Com	ments:									
							Date:			
Steven McClelland						March 24, 2	2020			
	Bureau of Licensing Services  Medical Devices Directorate									
Review Division – DLSD Communication										
Review Div	rision Screener Ac	tion:								
Review Div	<u>rision Screener Re</u>	esponse:								
									I	
								Date:		
1									1	



Technica	<mark>l Screeni</mark> n	<mark>ig (Revi</mark>	ew Division)				
Proposed reviewer:			Estimated Review Time (days):	Review Complexity:			
_				_			
Review Components Review Required Deficient			Comme	nts			
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							
	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							
Bundle Update/Modification – <b>To DLS manager</b>							
Rejection Rationale:							
Technical Screening Deficiencies:							
1.							

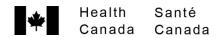




DLSD Deficiencies					
Over Paid Fee Deficiency					
1.					
Certificate Screening Checklist:					
☐ MDSAP ☐ Certificate Previous	ly Validated				
Cert # (new):	Cert Revisions / Comments (If Applicable):				
Cert. # (old):					
Replacing Existing Cert on File (Y/N):	_				
Criteria	Conforms	Comments/info for MDS			
First (most prominent) and full name on cert.	Comornis	Comments/into for MDS			
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"	<del>                                     </del>				
Expiry date. Field is identified as "Expiry", "Expiry					
Date", or "Recertification Due Date"	<del>                                     </del>				
Validity period ≤ 3 years.					
Certificate contains Unique Certificate Number.  Name, title, and signature of certification					
authority.					
All pages of certificate are present.	$\Box$				
pages of the smooth and probability		1			
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 "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"				
Name, title, and signature of certification authority				
Pagination (page x or y) included on all pages . All				
pages present.				
Method to verify validity				
100 12405 0 11/1 25	10 1 0	Y		
ISO 13485 Quality Managemen	nt System C	ertificate Scr	eening	
C		C+ # (-14)		
Cert. # (new):		Cert. # (old) :		
		Cert. # (old) :		
Cert. # (new):  Cert revisions:		Cert. # (old) :		
Cert revisions:				
Cert revisions:  First (most prominent) and full name on cert. matches		Effective dat	e of registration. Field is identifi	ied
Cert revisions:  First (most prominent) and full name on cert. matches			e of registration. Field is identifi	ied
Cert revisions:  First (most prominent) and full name on cert. matches application/licence, and label.		Effective dat as "Effective	e of registration. Field is identifi Date"	
Cert revisions:  First (most prominent) and full name on cert. matches application/licence, and label.		Effective dat as "Effective Expiry date.	e of registration. Field is identifi	
Cert revisions:  First (most prominent) and full name on cert. matches		Effective dat as "Effective Expiry date.	e of registration. Field is identifi Date" Field is identified as "Expiry" o	
Cert revisions:  First (most prominent) and full name on cert. matches application/licence, and label.  Address on cert, matches application, licence, and label.		Effective dat as "Effective Expiry date. "Expiry date'	e of registration. Field is identifi Date" Field is identified as "Expiry" o	
Cert revisions:  First (most prominent) and full name on cert. matches application/licence, and label.  Address on cert, matches application, licence, and label.		Effective dat as "Effective Expiry date. "Expiry date'	e of registration. Field is identificate"  Field is identified as "Expiry" of "Recertification due date".	
Cert revisions:  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	" "design"	Effective dat as "Effective Expiry date. "Expiry date' Validity peri	e of registration. Field is identificate.  Field is identified as "Expiry" of a Construction of the constr	
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Cert revisions:  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 (fr. conception) for Class III-IV.		Effective dat as "Effective Expiry date. "Expiry date' Validity peri Certificate co	e of registration. Field is identificate.  Field is identified as "Expiry" of or "Recertification due date".  od <= 3 years.  ontains unique certificate #.  Revised	
Cert revisions:  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 (fr. conception) for Class III-IV.  Scope is unambiguous and covers app. device. Scope does not corproduct names / models / numbers or licence numbers. Reference to attachmen	ntain specific	Effective dat as "Effective Expiry date. "Expiry date' Validity peri Certificate co	e of registration. Field is identificate.  Field is identified as "Expiry" of a contract of the contract of th	
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Cert revisions:  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 (fr. conception) for Class III-IV.  Scope is unambiguous and covers app. device. Scope does not corproduct names / models / numbers or licence numbers. Reference to attachmen acceptable.	ntain specific	Effective dat as "Effective Expiry date. "Expiry date' Validity peri Certificate co	e of registration. Field is identificate."  Field is identified as "Expiry" of a contain the contains unique certificate.  Revised  and signature of certification	
Cert revisions:  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 (fr. conception) for Class III-IV.  Scope is unambiguous and covers app. device. Scope does not core	ntain specific	Effective dat as "Effective Expiry date. "Expiry date' Validity peri Certificate con New Name, title, a authority. Number of ac	e of registration. Field is identificate."  Field is identified as "Expiry" of a contain the contains unique certificate.  Revised  and signature of certification	
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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.

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