

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

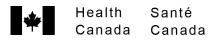
Application Information					
Application #: 312912 Licence #: 0	Licence Name: REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING 2019-NCOV	Application Type: U	Device Class: 2		
Manufacturer: BGI AMERICAS CORP		Company ID: 151819			

DLSD Application Validation								
Risk Class & Rule: Licence Type & Rati IVDD Rule 2(b) i TEST KIT		Rationale: Specia	Special Substances:			Application Format:		
	IEST KIT					_		
E. O.t.		Amendment Ma	anagem	ent				
Fee Category: Reason for Amendment:								
						T		
I								
		Bundle Infor	rmation					
Bundle Rationale:			-					
	Bundle table included		Create/Modify Financial Bundle Info					
Submission Completeness								
MDR	Requirement		Α	D	N/A	No	tes/Comments	
32	Application Form	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)		7					
		DLSD Recomn	nendatio	on				
Complete							•	
Notes/Comments:								
M. ROCHEFORT							Date:	
					April 15, 2020			
Bureau of Licensing Services Medical Devices Directorate					• ·			
	Revie	w Division – DLS	D Comn	nunicat	tion			
Review Division Screene	er Action:							
Review Division Screene	ar Response:							
							Date:	
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					
	Cla	ss IV			
Risk Assessment					
Quality Plan					
Biological Safety					
Manufacturing Process					
Process Validation				-	
Note to the Reviewer (e.g. predicate, referent SBD?	nce, cautio	ons, direc	tions) 🛛 Foreign	Review incl.	
Recommendation					
Bundle Update/Modification – To DLS manager					
Technical Screening Deficiencies:					
1.					



	DLSD Deficiencies
Over Paid Fee Deficiency	
1.	

Certificate Screening Checklist:

MDSAP

Certificate Previously Validated

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