



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

DLSD Application Validation			
Risk Class & Rule: IVDD Rule 2(b) i	Licence Type & Rationale: TEST KIT	Special Substances: <input type="text"/>	Application Format: <input type="text"/>
Amendment Management			
Fee Category: <input type="text"/>	Reason for Amendment: <input type="text"/>		
Bundle Information			
Bundle Rationale: <input type="text"/>	Related Applications Bundle table included? <input type="checkbox"/>	<input type="button" value="Create/Modify Financial Bundle Info"/>	

Submission Completeness					
MDR	Requirement	A	D	N/A	Notes/Comments
32	Application Form	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32	Submission Presentation (ToC, Cover Letter, Exec Summary)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32(3a/4a)	Device Description (as it relates to device listing in form)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32(3j/4p)	QMS Certificate MDSAP/CSA-ISO 13485:2016	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
32(3g/4o)	Labelling – 21(1a)(1b)(1c)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

DLSD Recommendation	
<input type="text" value="Complete"/>	

Notes/Comments:

M. ROCHEFORT Bureau of Licensing Services Medical Devices Directorate	Date: April 15, 2020
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Review Division – DLSD Communication

Review Division Screener Action:

Review Division Screener Response:

Review Division Screener Medical Devices Directorate	Date:
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Technical Screening (Review Division)

Proposed reviewer: <input type="text"/>	Estimated Review Time (days): <input type="text"/>	Review Complexity: <input type="text"/>
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Review Components	Review Required	Deficient	Comments
Class III + IV			
General Application Organization	<input type="checkbox"/>	<input type="checkbox"/>	
Device Description	<input type="checkbox"/>	<input type="checkbox"/>	
Marketing History	<input type="checkbox"/>	<input type="checkbox"/>	
Standards & Conformity Declaration	<input type="checkbox"/>	<input type="checkbox"/>	
Analytical Performance	<input type="checkbox"/>	<input type="checkbox"/>	
Physical & Chemical Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>	
Electrical & Radiation Safety	<input type="checkbox"/>	<input type="checkbox"/>	
Software Validation & Verification	<input type="checkbox"/>	<input type="checkbox"/>	
Biocompatibility & Pyrogenicity	<input type="checkbox"/>	<input type="checkbox"/>	
Sterilization, Packaging, & Shelf Life	<input type="checkbox"/>	<input type="checkbox"/>	
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>	
Stability	<input type="checkbox"/>	<input type="checkbox"/>	
Product Stability (Shelf Life)	<input type="checkbox"/>	<input type="checkbox"/>	
Usability	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical Studies	<input type="checkbox"/>	<input type="checkbox"/>	
Bibliography	<input type="checkbox"/>	<input type="checkbox"/>	
Near patient IVDD	<input type="checkbox"/>	<input type="checkbox"/>	
Labelling	<input type="checkbox"/>	<input type="checkbox"/>	

Class IV			
Risk Assessment	<input type="checkbox"/>	<input type="checkbox"/>	
Quality Plan	<input type="checkbox"/>	<input type="checkbox"/>	
Biological Safety	<input type="checkbox"/>	<input type="checkbox"/>	
Manufacturing Process	<input type="checkbox"/>	<input type="checkbox"/>	
Process Validation	<input type="checkbox"/>	<input type="checkbox"/>	

Note to the Reviewer (e.g. predicate, reference, cautions, directions) Foreign Review incl. SBD?

Recommendation

Bundle Update/Modification – To DLS manager

Technical Screening Deficiencies:

1.



DLSD Deficiencies

<input type="checkbox"/> 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):	