

CONSOLIDATED SCREENING FORM MEDICAL DEVICES

		Application Ir	oformat	ion				
Application #: 312781 Licence #: 0	Licence Name: NXTAG COV EXTENDED PANEL				Application Type:	Device Class: 3		
Manufacturer: LUMINEX MOLECULA	R DIAGNOS	STICS, INC.					Company ID: 0	
		DLSD Application	on Valid	lation				
Risk Class & Rule: Class III, IVDD Rule 2[I	Licence Type & Rationale: Spe Test Kit			ecial Substances:				
Fee Category:		Amendment M	anageme leason for		Iment:			
				Amene				•
		Bundle Info	rmation					
Bundle Rationale:	ationale: Related Applications Bundle table included			Create/Modify Financial Bundle Info			dle Info	
		Submission Co	mpletene	ess				
MDR	Requirem	ent	Α	D	N/A		s/Comments	6
32	Applicatior	n Form	•			autho instea with t	ot include io prization requ ad included a he information mation reque	document
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)					incluc manu	evice identifier is not cluded in the IFU and the anufacturer did not provide vice labels.	
		DLSD Recom	mendatio	n				
Incomple							٦	·
 The manufacture therefore the dev Quality Attestatio The address was 	er did not pr rice identifier ns were not not provide	a device identifier in the ovide product package is are not currently know provided (4(1)(i)) d where the device will Order was not included	labels, a vn be manuf	and the	IFU doe (4(1)(d)	es not o		æ identifiers
- Section 4(2)(a) of the Interim Order was not included (description of materials and packaging) Emily Smalling Date:								
Device Licensing Services Division Mar. 19, 2020 Medical Devices Bureau)20			
Review Division – DLSD Communication								
Review Division Screene	r Action:							
Review Division Screene	<u>r Respon</u> se:							



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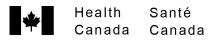
	Date:
Review Division Screener Medical Devices Bureau	



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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						
	Clas	ss IV				
Risk Assessment						
Quality Plan						
Biological Safety						
Manufacturing Process						
Process Validation				-		
Note to the Reviewer (e.g. predicate, reference, cautions, directions)						
Recommendation						
Bundle Update/Modification – To DLS manager						
Technical Screening Deficiencies:						
1.						

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DLSD Deficiencies					
Over Paid Fee Deficiency					
1.					

COVID-19 Medical Device & Manufacturer Details					
Class of Device	III				
Intended Use of Device (Section					
4(1)(f))	The Luminex NxTAG [®] CoV Extended Panel is intended for use on the Luminex [®] MAGPIX [®] instrument for the qualitative detection of nucleic acid from the 2019-nCoV in nasopharyngeal swabs collected from individuals with signs and symptoms of infection who are suspected of COVID-19.				

Device Name	Identifier	GMDN Code	PNC Code
NxTAG [®] CoV Extended		64747	88UJH
Panel			