Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **ALLPLEX 2019-NCOV ASSAY**	Application Number/Numéro de soumission **313001**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Covid-19 Interim Order Submission**
Manufacturer/Fabricant: **SEEGENE INC.**	Company ID/Identificateur d'entreprise: **128563**
Risk Class: **3**	Rationale: **IVDD Rule 2[b]i**
*Licence Type/Type d'homologation: **Single Device**	Rationale:

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

The Allplex™ 2019-nCoV Assay is an in vitro diagnostic (IVD) real-time RT-PCR test intended for the qualitative detection of nucleic acid from 2019-nCoV in Upper respiratory specimens e.g. Nasopharyngeal, Oropharyngeal swab, and Lower respiratory specimens e.g. Sputum from individuals with signs and symptoms of infection who are suspected of COVID-19.

OEM Licence Information	
OEM Licence Name :	OEM Manufacturer :
OEM Intended Use and/or Indications for Use	

Reason for Change		Comment(s)
Change to classification of a device	☐	
Manufacturer name change	☐	
License name change	☐	
Device name change	☐	
Change to the purpose/indication of license	☐	
Addition of device(s)	☐	
Deletion of device(s)	☐	

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

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 13485:2016 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.	☐	
Field labelled “Effective Date”	☐	
Field labelled “Expiry Date”	☐	
Validity period ≤ 3 years	☐	
Unique identification code labelled “certificate number” or “certification document number”	☐	☐ new ☐ revised
Name, title, and signature of certification authority	☐	
Pagination (page x or y) included on all pages . All pages present.	☐	
Method to verify validity	☐	

Screening Decision	
Accept	
Emily Smalling Device Licensing Services Division Medical Devices Bureau	**Date**: Mar. 26, 2020

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Check GMDN

GMDN Name	GMDN Code	GMDN Description	Issue	Action for Screener	Regulatory Action	Reference Material