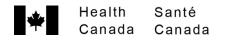
Application Information / Information de se	oumission
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission
PERKINELMER NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT	313232
Licence # / # de l'homologation:	Application Type/Type de soumission:
0	Interim Order
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:
PERKINELMER, INC.	152264
Risk Class:	Rationale:
3	Class III by IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation:	Rationale:
Test Kit 🔻	
Contains Controlled Substance(s)	Contains Biological Material(s)
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications	
The PerkinElmer® New Coronavirus Nucleic Acid Detime RT-PCR in vitro diagnostic test intended for the qualacid from the SARS-CoV-2 virus in human orophary in nasopharyngeal swab specimens collected from ind COVID-19 by their healthcare provider. Results are for the identification of SARS-CoV-2 RNA generally detectable in human oropharyngeal swab specimens during the acute phase of infection. Posi presence of SARS-CoV-2 RNA; clinical correlation wo other diagnostic information is necessary to determ Positive results do not rule out bacterial infection or viruses. Negative results do not preclude SARS-CoV-2 infect as the sole basis for patient management decisions. combined with clinical observations, patient history information. The PerkinElmer® New Coronavirus Nucleic Acid Kir qualified and trained clinical laboratory personnel sp trained in the techniques of real-time PCR and in vitu	litative detection of nucleic ngeal swab and lividuals suspected of A. SARS-CoV-2 RNA is and nasopharyngeal swab tive results are indicative of vith patient history and ine patient infection status. co-infection with other ion and should not be used Negative results must be , and epidemiological t is intended for use by pecifically instructed and

procedures.

OEM Lic	ence 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)	

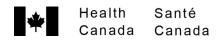


Deletion of device(s)	
Reason for Change	Comment(s)
Change in name and/or address of the	
Private Label Manufacturer	
Private Label License name change	
Private Label Device name change	
Addition of device(s)	
Deletion of device(s)	

Certificate Screening Checklist:

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		



Accept	•
Liem Whelan	Date : April 2 nd , 2020
Device Licensing Services Division Medical Devices Bureau	



Check GMDN

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