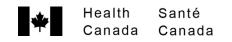


Cert # (new):

	***AMENDM	ENT- Add	ition of component
ıaA			formation de soumission
*Licence Name/Nom de	Application Numbe		
l'homologation:	314982		
License # / # do l'homologation:	Application Towar /T	uno do	mircion:
Licence # / # de l'homologation:  0	Application Type/T	ype ae sou	mission:
Manufacturer/Fabricant:	Company ID/Identi	ficateur d'e	entreprise:
Roche Diagnostics GmbH	114999		
Risk Class:	Rationale:	_	
4			ed and nucleic acidbased testing devices are Class IV
*Licence Type/Type d'homologation:	Rationale:	s unaer S	Schedule 1, Part 2, Rule 2(a)
test kit			
	<u> </u>		
Contains Controlled Substan	nce(s)	ontains [	Orug(s) Contains Biological Material(s)
This an application to amend	d IO 314982		
Addition of : PreciControl Ar	nti-SARS-CoV-2	(identif	er 09216928190)
	OFM	Licence I	nformation
OEM Licence Name :	OLIVI	LICCITCE II	OEM Manufacturer :
OEM Intended Use and/or Indications fo	r Use		
Peacon for Change			Commont(c)
Reason for Change Change to classification of a d	levice		Comment(s)
Manufacturer name change	IC VICE		
License name change			
Device name change			
Change to the purpose/indica	ition of		
license			
Addition of device(s)			
Deletion of device(s)			
Reason for Change			Comment(s)
Change in name and/or addre	ess of the		
Private Label Manufacturer			
Private Label License name ch	nange		
Private Label Device name cha			
Addition of device(s)	<del>-</del>		
Deletion of device(s)			
2.2 2. 4000(0)			1
Certificate Screenina Check	dist:		

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		□ navv. □ navisand
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	g Decision	
ACCEPT		▼
Roula Sifakis Vogel		<b>Date</b> : July 22, 2020
Davies Licensing Services Division		July 22, 2020
Device Licensing Services Division Medical Devices Bureau		

Santé Canada

Check GMDN

Code	GMDN Name	GMDN	GMDN Description	lssue	<b>Action for Screener</b>	Regulatory Action	Reference Material
		Code					