

Application Informa	ation /	Information d	le soumission
*Licence Name/Nom de l'homologation:			er/Numéro de soumission
1COPY COVID-19 QPCR KIT		312777	
Licence # / # de l'homologation: 0		nterim Order	Type de soumission:
Manufacturer/Fabricant:			tificateur d'entreprise:
1DROP INC.		L51664	
Risk Class:		Rationale: C lass III by IV E	DD Rule 2(b)(i)
*Licence Type/Type d'homologation:		Rationale:	2 3.0.0 = (1.0)(1)
Test Kit ▼			
		s Drug(s)	Contains Biological Material(s)
*Intended Use and/or Indications for Use/ Utilisation Prévue	et/ou Ind	dications	
1copy™ COVID-19 qPCR Kit is an I for qualitative analysis of E gene a (COVID-19) in extracted RNA from and oropharyngeal swab of patient infections.	nd Ro sputเ	dRp gene t im, nasop	for coronavirus haryngeal swab
OEM	Licence	Information	
OEM Licence Name :		OEM Manufac	turer :
OEM Intended Use and/or Indications for Use			
Reason for Change			Comment(s)
Change to classification of a device			Comment(s)
Manufacturer name change	$\vdash \vdash$		
License name change			
Device name change			
Change to the purpose/indication of			
license			
Addition of device(s)			
Deletion of device(s)			
Criteria		conforms	Comments/info for MDS
Issued to full name of manufacturer as it app	pears		
on application/licence and label.			
Issued to complete civic address matching application/licence and label.			
Criteria are ISO 13485:2003 or 2016 and Med	dical		
Devices Regulations – Part 1 – SOR 98/282	arcar		
Scope activities limited to design, developme	ent,		
manufacture, production, servicing, installat or distribution.	ion,		
Activities include "manufacture" or "product	tion"		
Activities include "design" or "development			
development" for class III/IV devices.			
Scope is unambiguous and covers app./lic.			
devices Does not contain product		I	

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			□ roviced
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			
ISO 13485 Quality Managemer	it System Cer	ctificate Scre	ening

ISO 13485 Quality Management System	Certificate Screening
Cert. # (new):	Cert. # (old):
Cert revisions:	
First (most prominent) and full name on cert. matches application/licence, and label.	Effective date of registration. Field is identified as "Effective Date"
Address on cert, matches application, licence, and label.	Expiry date. Field is identified as "Expiry" or "Expiry date". Or "Recertification due date".
Standard is (CAN/CSA) ISO 13485:2003 or 2016	Validity period <= 3 years.
Scope includes "manufacture" or "production". Scope includes "design" (fr. conception) for Class III-IV.	Certificate contains unique certificate #. New Revised
Scope is unambiguous and covers app. device. Scope does not contain specific product names / models / numbers or licence numbers. Reference to attachment is acceptable.	Name, title, and signature of certification authority.
Registrar is recognized.	Number of additional sites appearing on certificate:
SCC logo CMDCAS reference are present.	All pages of certificate are present.

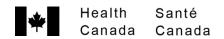
COVID-19 Mo	edical Device & Manufacturer Details
Class of Device	Class III
Intended Use of Device (Section 4(1)(f))	1copy™ COVID-19 qPCR Kit is an In-Vitro Diagnostic medical
	device
	for qualitative analysis of E gene and RdRp gene for coronavirus
	(COVID-19) in extracted RNA from sputum, nasopharyngeal swab
	and oropharyngeal swab of patients with suspected respiratory
	infections.

Device Name	Identifier	GMDN Code	PNC Code
1copy COVID-19 qPCR	M21MD100C	88UJH	64747



authority

Kit				
I		<u> </u>		
Reason for Change			Com	ment(s)
Change in name and/or address of the				()
Private Label Manufacturer				
Private Label License name change	П			
Private Label Device name change				
Addition of device(s)				
Deletion of device(s)				
Certificate Screening Checklist:				
Cert # (new):		Cert Revisions ,	/ Comments (If App	licable):
Cert. # (old):				
Replacing Existing Cert on File (Y/N):				
Criteria		conforms	Comm	nents/info for MDS
Issued to full name of manufacturer as it app	ears			
on application/licence and label.				
Issued to complete civic address matching				
application/licence and label.				
Criteria are ISO 13485:2016 and Medical Dev	ices			
Regulations – Part 1 – SOR 98/282				
Scope activities limited to design, developme	ent,			
manufacture, production, servicing, installati	on,			
or distribution.				
Activities include "manufacture" or "product	ion"			
Activities include "design" or "development a	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 "certifica	te	П	_	
number" or "certification document number			□ n	ew \square revised
Name, title, and signature of certification				
		I .	i	



Pagination (page x or y) included on all pages . All			
pages present.			
Method to verify validity			
Screening	Decision		
Accept			•
Liem Whelan		Date : March 27 th , 2020	
Device Licensing Services Division Medical Devices Bureau			

Santé Canada

Check GMDN

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