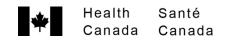


	Application Infor	mation / Information de soumission
*Licence Name/Nom de l'ho	omologation:	Application Number/Numéro de soumission
PANTHER FUSION SYS	TEM	312758
Licence # / # de l'homologa	tion:	Application Type/Type de soumission:
0		U-New-Priority
Manufacturer/Fabricant:		Company ID/Identificateur d'entreprise: 104123
HOLOGIC, INC. Risk Class:		Rationale:
3		IVDD Rule 2 {b}
*Licence Type/Type d'homo	ologation:	Rationale:
Test Kit	▼	
Contains Controlle	ed Substance(s)	Contains Drug(s) Contains Biological Material(s)
I I I I I I I I I I I I I I I I I I I		
	OFF	M Licence Information
OEM Licence Name :	<u> </u>	OEM Manufacturer :
OEM Intended Use and/or I	ndications for Use	·
Reason for Change		Comment(s)
Change to		
classification of a		
device		
Manufacturer		
name change		
License name		
change		
Device name	П	
change		
Change to the		
purpose/indication		
of license		
Addition of		
device(s)		
Deletion of		
device(s)	COMP 10 M 1	
Class of Davisa	COVID-19 Medic	cal Device & Manufacturer Details
Class of Device Intended Use of		nd qualitatiove detection of RNA from the SARS-CoV-2
Device (Section		ind qualitatiove detection of RNA from the SARS-Cov-2 (19-nCoV) isolated and purified from nasopharyngeal(NP) and
4(1)(f))		ab specimens obtained from individuals who meet COVID-19
.(*)(*))	clinical and/or epidemic	

Device Name	Identifier	GMDN Code	PNC Code
Panther Fusion SARS-			88UJH
CoV-2			
Primer Probe Reagent			64747
	PRD-06391		
Panther Fusion SARS-			
CoV-2			



Assay Controls	DDD 06404				64748	
Panther Fusion Open	PRD-06404					
Access RNA/DNA	PRD-04303					
Enzyme Reagent	11000.000				64747	
Cartridge						
Panther Fusion Oil					64747	
Audines Oil Desembleit	PRD-04335 PRD-04304				64747	
Aptiman Oil Reagent kit Panther Fusion SARS-	PKD-04304				64748	
CoV-2	PRD-04332				04740	
Internal Control-S	110 04332					
Panther Fusion SARS-					64747	_
CoV-2						
Extraction Reagent-S	PRD-04331					
Panther Fusion SARS-					No code	
CoV-2 Elution Buffer	PRD-04334					
Elution Buller	1 KD-04334					
D (C)						
Reason for Change				Com	ment(s)	
Change in name and/or						
Private Label Manufactu						
Private Label License nar	me change					
Private Label Device nam	ne 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)·					
mephasing zinsting control in the (1)						
				I		
Criteria	•		conforms	Comm	nents/info for MDS	
Issued to full name of ma		ears				
on application/licence ar						
Issued to complete civic						
application/licence and I						
Criteria are ISO 13485:20		ices				
Regulations – Part 1 – SC						
Scope activities limited t	o design, developme	ent,				
manufacture, production	n, servicing, installati	on,				
or distribution.						
Activities include "manu	facture" or "product	ion"				
Activities include "design	· ·	and				
development" for class I	II/IV devices.					
Scope is unambiguous ar	nd covers app./lic.					
devices. Does not contai	n product					
names/models/licence n	umbers.					



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	g Decision	
Accept		▼
Florianne Uwera		Date : 2020-03-19
Device Licensing Services Division Medical Devices Bureau		

Santé Canada

Check GMDN

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