



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: PANTHER FUSION SYSTEM	Application Number/Numéro de soumission 312758
Licence # / # de l'homologation: 0	Application Type/Type de soumission: U-New-Priority
Manufacturer/Fabricant: HOLOGIC, INC.	Company ID/Identificateur d'entreprise: 104123
Risk Class: 3	Rationale: IVDD Rule 2 {b}
*Licence Type/Type d'homologation: <input type="text" value="Test Kit"/>	Rationale:
<input type="checkbox"/> Contains Controlled Substance(s) <input type="checkbox"/> Contains Drug(s) <input type="checkbox"/> Contains Biological Material(s)	
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications	

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	<input type="checkbox"/>	
Manufacturer name change	<input type="checkbox"/>	
License name change	<input type="checkbox"/>	
Device name change	<input type="checkbox"/>	
Change to the purpose/indication of license	<input type="checkbox"/>	
Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	

COVID-19 Medical Device & Manufacturer Details	
Class of Device	Class III
Intended Use of Device (Section 4(1)(f))	Intended for the rapid and qualitative detection of RNA from the SARS-CoV-2 virus(formely called 2019-nCoV) isolated and purified from nasopharyngeal(NP) and oropharyngeal(OP) swab specimens obtained from individuals who meet COVID-19 clinical and/or epidemiological criteria.

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



<u>Assay Controls</u>	PRD-06404		64748
<u>Panther Fusion Open Access RNA/DNA Enzyme Reagent Cartridge</u>	PRD-04303		64747
<u>Panther Fusion Oil</u>	PRD-04335		64747
<u>Aptiman Oil Reagent kit</u>	PRD-04304		64747
<u>Panther Fusion SARS-CoV-2 Internal Control-S</u>	PRD-04332		64748
<u>Panther Fusion SARS-CoV-2 Extraction Reagent-S</u>	PRD-04331		64747
<u>Panther Fusion SARS-CoV-2 Elution Buffer</u>	PRD-04334		No code

Reason for Change		Comment(s)
Change in name and/or address of the Private Label Manufacturer	<input type="checkbox"/>	
Private Label License name change	<input type="checkbox"/>	
Private Label Device name change	<input type="checkbox"/>	
Addition of device(s)	<input type="checkbox"/>	
Deletion of device(s)	<input type="checkbox"/>	

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.	<input type="checkbox"/>	
Issued to complete civic address matching application/licence and label.	<input type="checkbox"/>	
Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282	<input type="checkbox"/>	
Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution.	<input type="checkbox"/>	
Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices.	<input type="checkbox"/>	
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.	<input type="checkbox"/>	



Auditing Organisation is Authorized or Recognized	<input type="checkbox"/>	
Statement of Authorization or Recognition.	<input type="checkbox"/>	
Field labelled "Effective Date"	<input type="checkbox"/>	
Field labelled "Expiry Date"	<input type="checkbox"/>	
Validity period ≤ 3 years	<input type="checkbox"/>	
Unique identification code labelled "certificate number" or "certification document number"	<input type="checkbox"/>	<input type="checkbox"/> new <input type="checkbox"/> revised
Name, title, and signature of certification authority	<input type="checkbox"/>	
Pagination (page x or y) included on all pages . All pages present.	<input type="checkbox"/>	
Method to verify validity	<input type="checkbox"/>	

Screening Decision	
<input type="text" value="Accept"/>	
<input type="text" value="Florianne Uwera"/>	Date: 2020-03-19
Device Licensing Services Division Medical Devices Bureau	



Check GMDN

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