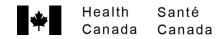


Application Information	/ Information de soumission
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission
SPARTAN COVID-19 SYSTEM	313012
Licence # / # de l'homologation:	Application Type/Type de soumission:
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:
SPARTAN BIOSCIENCE INC.	131730
Risk Class:	Rationale:
3	IVDD Rule 2[b]i)
*Licence Type/Type d'homologation:	Rationale:
Single Device	
Contains Controlled Substance(s)	ns Drug(s) Contains Biological Material(s)
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou	Indications
The Spartan COVID-19 System is internucleic acids from SARS-CoV-2, obtaicollected from individuals suspected of	ned from an oropharyngeal swab sample
the identification of a patient's CYP2C	a qualitative in vitro diagnostic test for 19 *2, *3, and *17 genotypes determined
from genomic DNA obtained from a bu	iccai swab sampie.
	•
OEM Licer	nce Information
	•
OEM Licer	nce Information
OEM Licer OEM Licence Name : OEM Intended Use and/or Indications for Use	OEM Manufacturer :
OEM Licer OEM Licerce Name : OEM Intended Use and/or Indications for Use Reason for Change	OEM Manufacturer : Comment(s)
OEM Licer OEM Licence Name : OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device	OEM Manufacturer :
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change	OEM Manufacturer : Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change	OEM Manufacturer : Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change	OEM Manufacturer : Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change License name change Device name change	OEM Manufacturer : Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change License name change Device name change	Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change Change to classification of a device Manufacturer name change License name change Device name change Change to the purpose/indication of	Comment(s)
OEM Licer OEM Licence Name: OEM Intended Use and/or Indications for Use Reason for Change 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)	Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change 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)	Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change 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)	Comment(s)
OEM Licer OEM Licerce Name: OEM Intended Use and/or Indications for Use Reason for Change 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)	Comment(s)

Device Name	Identifier	GMDN Code	PNC Code
Spartan COVID-19 Cube Platform	51C01001	64756	88UJH
Spartan COVID-19 Test Kit (20 Tests)	51C02001		88UJH
Spartan COVID-19 Swab (20 Swab sets)	51C02002		88UJH
Spartan Cube CYP2C19 Assay	ASM-00095		88UJH
Test Kit	ASM-00101		88UJH



Swab Kit External Control Kit	ASM-00103 ASM-00099				88UJH
				•	
Reason for Change				Comr	ment(s)
Change in name and/or a					
Private Label Manufactur					
Private Label License nan					
Private Label Device nam	e change				
Addition of device(s)					
Deletion of device(s)					
Certificate Screening C	hecklist:				
Cert # (new):			Cert Revisions ,	/ Comments (If Appli	cable):
Cert. # (old):					
Replacing Existing Cert on File (Y/N	I):				
Criteria			conforms	Comm	ents/info for MDS
Issued to full name of ma	nufacturer as it appe	ears			
on application/licence an	d label.				
Issued to complete civic a	address matching				
application/licence and la	abel.				
Criteria are ISO 13485:20	16 and Medical Devi	ces			
Regulations – Part 1 – SO	R 98/282				
Scope activities limited to	design, developmer	nt,			
manufacture, production	, servicing, installation	n,			
or distribution.					
Activities include "manuf	•				
Activities include "design	•	nd			
development" for class II					
Scope is unambiguous an					
devices. Does not contain	•				
names/models/licence no	umbers.				
Auditing Organisation is A	Authorized or				
Recognized					
Statement of Authorization					
Field labelled "Effective D	Date"				
Field labelled "Expiry Dat	e"				
Validity period ≤ 3 years					
Unique identification cod	le labelled "certificate	e			w Drovised
number" or "certification	document number"			□ □ ne	w □ revised
Name, title, and signature	e of certification				
authority					
Pagination (page x or y) in	ncluded on all pages	. All			
pages present.					
Method to verify validity					



Screening Decision	
Accept	•
Amanda Mooney	Date : March 26, 2020
Device Licensing Services Division Medical Devices Bureau	

Health	Canada
1)-

Santé Canada

Check GMDN

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