



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: SPARTAN COVID-19 SYSTEM	Application Number/Numéro de soumission 313012
Licence # / # de l'homologation: 0	Application Type/Type de soumission:
Manufacturer/Fabricant: SPARTAN BIOSCIENCE INC.	Company ID/Identificateur d'entreprise: 131730
Risk Class: 3	Rationale: IVDD Rule 2[b]i)
*Licence Type/Type d'homologation: <input type="text" value="Single Device"/>	Rationale:
<input type="checkbox"/> Contains Controlled Substance(s) <input type="checkbox"/> Contains Drug(s) <input type="checkbox"/> Contains Biological Material(s)	
<p>*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications</p> <p>The Spartan COVID-19 System is intended for the qualitative detection of nucleic acids from SARS-CoV-2, obtained from an oropharyngeal swab sample collected from individuals suspected of COVID-19.</p> <p>The Spartan Cube CYP2C19 System is a qualitative in vitro diagnostic test for the identification of a patient's CYP2C19 *2, *3, and *17 genotypes determined from genomic DNA obtained from a buccal swab sample.</p>	

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	III
Intended Use of Device (Section 4(1)(f))	

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	ASM-00103	88UJH
External Control Kit	ASM-00099	

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="Amanda Mooney"/>	Date: March 26, 2020
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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