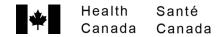


Application Informa	ation / Info	ormation de soumission						
*Licence Name/Nom de l'homologation: ADVIA CENTAUR SARS-COV-2 TOTAL (COV2T) TOTAL QUALITY CONTROL (COV2T QC)	l'homologation: SARS-COV-2 TOTAL (COV2T) / ADVIA CENTAUR SARS-COV-2							
Licence # / # de l'homologation:			Application Type/Type de soumission: Interim Order					
Manufacturer/Fabricant: SIEMENS HEALTHCARE DIAGNOSTICS INC.			Company ID/Identificateur d'entreprise:					
Risk Class:			Rationale: Classification Rule IVDD Rule 2(b)(i)					
*Licence Type/Type d'homologation:  Test Kit			Rationale:					
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)								
use in the qualitative detection of to SARS-CoV-2 in human serum and particles and ADVIA Centaur® XP and ADVIA Centies assay is intended as an aid in response to SARS-CoV-2, indicating Test results should be interpreted in patient history, epidemiological information result does not exclude the SARS-CoV-2 and should not be used decisions. SARS-CoV-2 antibodies positive result may be indicative of	olasma ntaur® identify g recen in conju ormatio ne possi ed as th may be	(EDTA and lithium XPT systems. ring patients with a t or prior infection inction with clinical and other laborations of exposure to sole basis for part detectable after in	n adaptive immune I observations, story findings. A to or infection with tient management					
OEM	Licence In	formation						
OEM Licence Name :	C	DEM Manufacturer :						
OEM Intended Use and/or Indications for Use								
Reason for Change		Comr	ment(s)					
Change to classification of a device		301111	110111(0)					
Manufacturer name change								
License name change								
Device name change								
Change to the purpose/indication of								
license								
Addition of device(s)								
Deletion of device(s)								
Reason for Change		Comr	ment(s)					
Change in name and/or address of the		Comi	nenu(s)					
Private Label Manufacturer								
Private Label License name change								
Private Label Device name change								



Addition of device(s)						
Deletion of device(s)						
Certificate Screening Checklist:						
Cert # (new):		Cert Revisions / Comments (If Applicable):				
Cert. # (old):						
Replacing Existing Cert on File (Y/N):						
			1			
Criteria		conforms		Comments	/info for MDS	
Issued to full name of manufacturer as it app on application/licence and label.	ears					
Issued to complete civic address matching						
application/licence and label.						
Criteria are ISO 13485:2016 and Medical Dev Regulations – Part 1 – SOR 98/282	rices					
Scope activities limited to design, developme manufacture, production, servicing, installati or distribution.						
Activities include "manufacture" or "product Activities include "design" or "development a 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		П				
Unique identification code labelled "certificanumber" 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						
			1			
Scre	eening	Decision				
Accept					▼	
Jiazhen Minnie Dai				<b>Date</b> :2020	0-06-03	
Device Licensing Services Division Medical Devices Bureau						



*
7

Santé Canada

Health Canada Check GMDN

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