



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T)	Application Number/Numéro de soumission 316782
Licence # / # de l'homologation: 0	Application Type/Type de soumission: Interim Order
Manufacturer/Fabricant: SIEMENS HEALTHCARE DIAGNOSTICS INC.	Company ID/Identificateur d'entreprise: 113434
Risk Class: 3	Rationale: Classification Rule IVDD Rule 2(b)(i)
*Licence Type/Type d'homologation: <div style="border: 1px solid black; padding: 2px; display: inline-block;"> Test Kit </div>	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 <p>The Dimension Vista SARS-CoV-2 Total antibody assay (CV2T) is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 virus in human serum and plasma (EDTA, lithium heparin) using the Dimension Vista system. This assay is intended as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.</p> <p>Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information and other laboratory findings. A negative result does not exclude the possibility of exposure to or infection with SARS-CoV-2 and should not be used as the sole basis for patient management decisions. SARS-CoV-2 antibodies may be detectable after infection and a positive result may be indicative of acute or recent infection.</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"/>	

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	
<div style="border: 1px solid black; padding: 2px;"> Accept ▼ </div>	
<div style="border: 1px solid black; padding: 2px;"> Jiazhen Minnie Dai ▼ </div>	Date: 2020-06-25
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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