



Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: PANBIO COVID-19 AG RAPID TEST DEVICE (NASOPHARYNGEAL)	Application Number/Numéro de soumission 320577
Licence # / # de l'homologation: 0	Application Type/Type de soumission: Interim Order
Manufacturer/Fabricant: ABBOTT RAPID DIAGNOSTICS JENA GMBH	Company ID/Identificateur d'entreprise: 161646
Risk Class: 4	Rationale: Rule 2(a)
*Licence Type/Type d'homologation: Test Kit	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>Panbio™ COVID-19 Ag Rapid Test Device is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.</p> <p>The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2</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):	

See product dossier for all technical information

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;"> Mohammad Jamal ▼ </div>	Date: 2020-09-02
Device Licensing Services Division Medical Devices Directorate	



Review Division – DLSD Communication	
<u>Review Division Screener Action:</u>	
<u>Review Division Screener Response:</u>	
<hr/> Review Division Screener Medical Devices Directorate	Date:



Check GMDN

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