TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	**Artron Laboratories Inc.** 3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada
Report Number:	**50353284 001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	COVID-19 IgM/IgG Antibody Test
Type(s)/Model(s):	Cassette
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.18.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CE-COVID-19-A03-51-322, Revision 01, Dated 2020-Mar-15) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

Yuhong CHEN
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TÜV Rheinland (China) Ltd.

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Product Safety & Quality Assurance TÜV Rheinland III Approved

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