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# CE Technical Documentation Review Report

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| Applicant: | **Shijiazhuang Hipro Biotechnology Co., Ltd.**<br>No.3 Building, Block C, Fangyi Science Park,<br>No.313 Zhujiangdadao Road, Hi-tech Zone,<br>Shijiazhuang, 050000, Hebei, China |
| Report Number: | **50350275-001** |
| 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): | 2019-nCoVIgM / IgG Antibody Test Kit (Colloidal Gold)<br>2019-nCoVIgM / IgG Antibody Test Kit (Nephelometry Immunoassay Method) |
| Type(s)/Model(s): | 20 Tests/Kit |
| Classification: | Other IVD products<br>(according to manufacturer's declaration) |
| Examination period: | Mar.17.2020 |
| Date of expiry: | May.26.2024 |
| Review result: | During the examination of the provided Technical Documentation (QJ/HP-CE-45, Revision A/0, Dated 2020-Feb-27) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected. |

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