MedPath

# EC-Registration Certificate

**Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Article 10**

**No. R A001 98/A Rev. 01**

## Manufacturer: Shenzhen Highcreation Technology Co.,Ltd

7th Floor,Building A ,NO.16-1,jinhui rd,Jinsha Community,Kenzi Sub-district,Pingshan District, Shenzhen,P.R.China

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) and has allocated registration numbers shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

**Date,** 2020-04-07

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
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# Appendix A

| Products | Classifi-cation | EDMA Code | Form No. |
|---|---|---|---|
| Novel Corona- virus IgM/IgG Combo Rapid Test | others | 15-70-03-90-00 | 00154605 |

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