MedPath

EC-Registration Certificate

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

No. R A001 39/A Rev. 01

Manufacturer: Biotech Medical Equipment (Zhejang) Co., Ltd.

Building 1, Wanshili Technology Park, No.619
Wangmei Rd., Yuhang District, Hangzhou, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): See Appendix A

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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, 2020-03-19

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

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Appendix A

Products	Class	EDMA Code	Form No.	Registration number
Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test	Others	15-70-03-90-00	00154146	DE/CA61/1M50/149

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