MedPath

EC-Registration Certificate

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

No. R A000 03/C Rev. 01

Manufacturer: Cellex, Inc.

76 TW Alexander Drive, Research Triangle Park,
NC 27709-0002, USA

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) 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, 2020-03-25

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

Products	Classification	EDMA Code	DIMDI Form No.
Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	others	15-04-80-90-00	00153907

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