

EC-Declaration of Conformity

1 Doc. ID

REG-4732

2 Manufacturer

Site address: Nordic Biomarker, Vildmannavägen 1, 903 47 Umeå, Sweden

3 Product

MRX Green vWF Antigen, Article no K5052

MRX vWF Antigen Calibrator, Article no K5053

4 Product Description

MRX Green vWF Antigen is a latex immunoassay for quantitative determination of von Willebrand Factor (vWF) Antigen in citrated human plasma as an aid in diagnosis of von Willebrand Disease (vWD). MRX Green vWF Antigen is intended to be used by professional laboratory personnel using coagulation analysers with turbidimetric detection in the 500 – 700 nm wavelength range.

MRX vWF Antigen Calibrator is intended for calibration of the MRX Green vWF Antigen reagent in percent. MRX vWF Antigen Calibrator are intended to be used by professional laboratory personnel using coagulation analysers.

5 Classification

“All other IVD Medical Devices” (not listed in Annex II, and not for self-testing)

6 Conformity assessment route

According to Annex III of the IVD Directive 98/79/EC (LVFS 2001:7).

7 Declaration

We declare under our sole responsibility the compliance of the medical devices concerned with the applicable requirements in the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2001:7 of the Swedish Medical Products Agency. Hereby, the medical device complies with the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices.

Any modification to the device, not authorised by us, will invalidate this declaration.

Umeå, 2022-03-29

DocuSigned by:
Rikard Rodén

 Signer Name: Rikard Rodén
Signing Reason: I approve this document
Signing Time: 2022-03-29 | 15:26:18 CEST
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CEO Nordic Biomarker

NORDIC BIOMARKER	REG-4732		Issued: 2022-03-29	Version: 1.0
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8 Document Approval

Review	Approval	Release
DocuSigned by: <i>Karin Öhman</i>  Signer Name: Karin Öhman Signing Reason: I have reviewed this document Signing Time: 2022-03-29 16:08:40 CEST 0EF4E6D7B3AD425DB0A8D0313AE34A45	CEO DocuSigned by: <i>Rikard Rodén</i>  Signer Name: Rikard Rodén Signing Reason: I approve this document Signing Time: 2022-03-29 15:26:25 CEST D545BAE7F1EA4BE6B705D16113A06FBA	Quality Assurance DocuSigned by: <i>Linn Rautio</i>  Signer Name: Linn Rautio Signing Reason: I approve this document Signing Time: 2022-03-29 19:47:17 CEST 5C585405870F41C297A991617F7BB45B