

EC-Declaration of Conformity

1 Doc. ID

REG-3727

2 Manufacturer

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

3 Product

MRX Blue Free Protein S, Article no K5010

4 Product Description

MRX Blue Free Protein S is a latex immunoassay (LIA) for the quantitative determination of free Protein S in human plasma.

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 device 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, 2021-03-26

CEO

DocuSigned by:

Rikard Rodén



Signer Name: Rikard Rodén
Signing Reason: I approve this document
Signing Time: 2021-03-26 | 09:36:03 CET

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NORDIC BIOMARKER	REG-3727	Article: K5010	Issued: 2021-03-26	Version: 1.0
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8 Document Approval

Review	Approval	Release
DocuSigned by: <i>Karin Ohman</i>  Signer Name: Karin Ohman Signing Reason: I have reviewed this document Signing Time: 2021-03-26 08:29:47 CET 0EF4E6D7B3AD425DB0A8D0313AE34A45	CEO DocuSigned by: <i>Rikard Rodén</i>  Signer Name: Rikard Rodén Signing Reason: I approve this document Signing Time: 2021-03-26 09:36:13 CET D545BAE7F1EA4BE6B705D16113A06FBA	Quality Assurance DocuSigned by: <i>Linn Rautio</i>  Signer Name: Linn Rautio Signing Reason: I approve this document Signing Time: 2021-03-26 09:37:35 CET 5C585405870F41C297A991617F7BB45B