

EC-Declaration of Conformity

1 Doc. ID

REG-4188

2 Manufacturer

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

3 Product

MRX Protein C, Article no K5020

MRX Protein C Calibrator, Article no K5023

4 Product Description

MRX Protein C is a chromogenic test for quantitative determination of Protein C activity in citrated human plasma as an aid in diagnosis of Protein C deficiency. MRX Protein C is intended to be used by professional laboratory personnel using automated coagulation analyzers measuring at 405 nm.

MRX Protein C Calibrator is intended for calibration of the MRX Protein C reagent in percent. The calibrator is intended to be used by professional laboratory personnel using automated coagulation analyzer.

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, 2021-10-27

DocuSigned by:
Rikard Rodén
 Signer Name: Rikard Rodén
Signing Reason: I approve this document
Signing Time: 2021-10-27 | 11:25:04 CEST
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CEO Nordic Biomarker

NORDIC BIOMARKER	REG-4188		Issued: 2021-10-27	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: 2021-10-26 16:26:58 CEST 0EF4E6D7B3AD425DB0A8D0313AE34A45	CEO DocuSigned by: <i>Rikard Rodén</i>  Signer Name: Rikard Rodén Signing Reason: I approve this document Signing Time: 2021-10-27 11:25:14 CEST D545BAE7F1EA4BE6B705D16113A06FBA	Quality Assurance DocuSigned by: <i>Jessica Wikteliuss</i>  Signer Name: Jessica Wikteliuss Signing Reason: I approve this document Signing Time: 2021-10-27 13:00:34 CEST 5DADDB0BECB44B4AA1E2F9CC1E1F5BD8