EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 733600 R000

Manufacturer: Geneproof a.s.

Address:
Vídeňská 101/119
619 00 Brno - Dolní Heršpice
Czech Republic

Single Registration Number: CZ-MF-000002370

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-11**

Current Issue Date: **2024-01-15**

Starting Validity Date: **2024-01-15**

Expiry Date: **2028-01-10**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0105 - Infectious Diseases. IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS).	Nucleic Acid Devices intended to be used for confirmation and identification of infectious agents.
W0103, Haematology / Haemostasis / Immunohematology / Histology / Cytology IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS).	Nucleic Acid Devices intended for genotyping patients as an aid to for diagnosing suspected thrombophilia and haemorrhagic disorders.
Class B devices	**Intended purpose**
IVR 0702 - Devices which are controls without a qualitative assigned value.	Devices to be used as internal controls for quality control of DNA/RNA extraction and efficiency of the PCR amplification.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-11	3268064	Issued
Current	30062238	Supplemented –Addition of the W0103 IVP 3011 group.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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