

# EU Quality Management System Certificate

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

## IVDR 733600 R000

**Manufacturer:** Geneproof a.s.

**Address:**

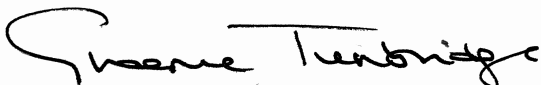
Vídeňská 101/119  
619 00 Brno - Dolní Heršpice  
Czech Republic

**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: **2023-01-11**

Starting Validity Date: **2023-01-11**

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

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### Device Schedule: Class D, C and B devices

#### Class C devices

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).

#### Class B devices

IVR 0702 - Devices which are controls without a qualitative assigned value.

#### Intended purpose

Nucleic Acid Devices intended to be used for confirmation and identification of infectious agents.

#### Intended purpose

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
Current	3268064	Issued



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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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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.