SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 22 003 0135

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV excluding section 4 and section 6

Certificate holder: **DIALAB Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m.b.H**

IZ NOE-Sued Hondastrasse Objekt M55, A-2351 Wiener Neudorf, Austria

Related audit report: AIVDD 2022NB003 I01

Other Facility(ies): -

The certificate was issued with respect to the following scope:

HIV 1&2 Ag/Ab

This certificate is effective from 24 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 24 May 2022.

Certification has been authorized by

Digitally signed by Radovan Máčaj

Radovan Macaj
Head of Notified body

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Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

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Additional information on certification

Related to certificate number:

IVDD 22 003 0135

Description of product(s) within the certification scope:

HIV 1&2 Ag/Ab is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of antigens and/or antibodies to Human Immunodeficiency Viruses (HIV) type 1 (group M -O) and/or type 2 in human serum or plasma samples. The method is also known as 4th generation ELISA for HIV detection. The kit is intended for screening of blood donors and as an aid in the diagnosis of clinical conditions related to infection with HIV-1 and/or HIV-2 –the etiological agents of the acquired immunodeficiency syndrome (AIDS).

Types/Categories/Models:	Z04380 (96 wells) Z13382 (480 wells)
Classification:	List A
Validity conditions:	-

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Initial version of the certificate was effective from 24 May 2022.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.