By Royal Charter

EU Quality Management System Certificate

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

IVDR 785602 R000

Manufacturer: ARK Diagnostics, Inc.

Address:
48089 Fremont Blvd
Fremont
California
94538
USA

Single Registration Number: US-MF-000023925

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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 Global Regulatory & Quality

First Issue Date: **2024-12-13**

Current Issue Date: **2024-12-13**

Starting Validity Date: **2024-12-13**

Expiry Date: **2029-12-12**

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Device Schedule: Class D, C and B devices

Class C devices	**Intended purpose**
W0102 – Immunochemistry IVP 3007 - In vitro diagnostic devices which require knowledge of immunoassays	In vitro diagnostic immunoassays, calibrators and controls intended for determination of medicinal products for therapeutic drug monitoring
Class B devices	**Intended purpose**
IVR 0605 – In vitro diagnostic devices intended to be used for monitoring of levels of medicinal products, substances or biological components	In vitro diagnostic immunoassays, calibrators and controls intended for detection of medicinal products for drug monitoring

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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	3852929	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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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