By Royal Charter

EU Quality Management System Certificate

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

IVDR 758040 R000

Manufacturer: R&D Systems, Inc.

Address:
614 McKinley Place N.E.
Minneapolis
Minnesota
55413
USA

Single Registration Number: US-MF-000024485

EU Authorised Representative: Bio-Techne SAS

Address:
19 Rue Louis Delourmel
35230 Noyal Chatillon Sur Seiche
France

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: **2024-10-01**

Current Issue Date: **2024-10-01**

Starting Validity Date: **2024-10-01**

Expiry Date: **2029-09-30**

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Device Schedule: Class D, C and B devices

Class B near-patient test devices	**Intended purpose**
CBC-PIX	See IVDR 758045
Class B devices	**Intended purpose**
IVR 0608 – Devices intended to be used for the screening, determination or monitoring of physiological markers.	Spectroscopy, physical chemistry, and flow cytometry control/calibrator devices for screening, determination or monitoring of physiological markers related to hematology.

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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	3539436	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.