By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 758045 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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:

Intended Purpose as per the Instructions for Use:

CBC-PIX is an assayed whole blood control designed to monitor values on the PixCell HemoScreen analyzer. CBC-PIX is not used in the diagnosis, aid in the diagnosis, prognosis, prediction of disease or physiological state of patients. It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. This control is a stable, whole blood preparation that can be used to verify the hematology analyzer is working as intended. Users run the control to ensure the instrument is performing per its intended use. No specimen is required and there is no testing population. Please refer to the assay table for specific instrument models.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
CBC-PIX	PIX002	IVR 0608	Class B near-patient test	081576202PIX0025V
CBC-PIX	0PI111TA3, 0PI222TA3, 0PI030TA3, 0PI600TA3, 0PI060TA3, 0PI006TA3, 0PI444TA3, 0PI606TA3, 0PI660TA3, 0PI066TA3, 0PIC00TA3, 0PI0C0TA3, 0PI00CTA3	IVR 0608	Class B near-patient test	0815762020PIBL

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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	3539484	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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