

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cyvek Inc.
5 Technology Drive
Wallingford
Connecticut
06492
USA

Holds Certificate Number:

MD 776823

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of in vitro diagnostic immunoassay cartridges. Design and development of automated in vitro diagnostic immunoassay instruments for the analysis of biomarker detection used in the field of biomedical therapies including cancer, neurodegenerative diseases, immune-related and infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-10-11

Latest Revision Date: 2023-10-11

Effective Date: 2023-10-11

Expiry Date: 2026-10-10

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