By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

CTK Biotech, Inc.
13855 Stowe Dr.
Poway
California
92064
USA

Holds Certificate Number: FM 517416

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

Research, design and development, manufacturing and distribution of in vitro diagnostic reagents, controls, test kits and instruments for use in the areas of Autoimmune / Allergy, Cardiac Markers, Fertility, Infectious Diseases, Endocrinology, and Oncology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2007-07-26
Latest Revision Date: 2025-03-18

Effective Date: 2025-05-16
Expiry Date: 2028-05-15

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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