



# Certificate of Registration

### QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TCS Biosciences Limited Botolph Claydon Buckingham MK18 2LR United Kingdom

Holds Certificate Number:

FS 28907

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The procurement, manufacture and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Original Registration Date: 1994-08-11 Latest Revision Date: 2019-01-17



Andrew Launn, EMEA Systems Certification Director

Effective Date: 2019-01-27 Expiry Date: 2022-01-26

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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 <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.





# Certificate of Registration

## ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TCS Biosciences Ltd Botolph Claydon Buckingham MK18 2LR United Kingdom

Holds Certificate Number:

EMS 590359

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The procurement, manufacture and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Original Registration Date: 2013-06-10 Latest Revision Date: 2019-01-18



Andrew Launn, EMEA Systems Certification Director

Effective Date: 2019-01-27 Expiry Date: 2022-01-26

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# SELF DECLARATION OF CONFORMITY

products: We declare under our sole responsibility in accordance with MHRA Registration Number IVD 000100 that the following CE marked

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EDMA code(s) EDI	EDMA description	TCS product code and description
14.50.01.90 Oth	Other Controls/Standards/Calibrators,	Selectrol - All MM codes
Mic	Vlicrobiology	

diagnostic medical devices. Regulations 2002 (SI 2002 No.618) and The Medical Devices (Amendment) Regulations 2003 (SI 2003 No.1697) for in-vitro conform to the relevant provisions of the In-vitro Diagnostic Medical Devices Directive 98/79/EC and The Medical Devices

as certified by BSi, certificate number FS 28907. Directive 98/79/EC and continued maintenance of an approved Quality Management System meeting the requirements of ISO 9001, This declaration is made on the basis of meeting the requirements of Annexes I and III of the In-Vitro Diagnostic Medical Devices

Name: Position: Signed by: Signed by: Name: Position: Managing Director **Regulatory Affairs Manager** Sue Brown Lynda Preston bon Date: Date: 30.04.2016 30.04.2016

lss 2/30.04.16