

## STATEMENT

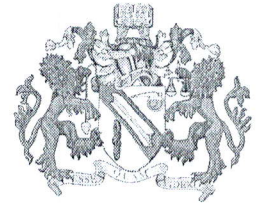
We, TCS Biosciences Ltd., having a registered office at Botolph Claydon, Buckingham, MK 18 2LR, England assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova, as Authorized Representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date : 21 August 2018

Signature: *Jul Brown*

bsi.



By Royal Charter

# 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:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2013-06-10

Latest Revision Date: 2019-01-18

Effective Date: 2019-01-27

Expiry Date: 2022-01-26



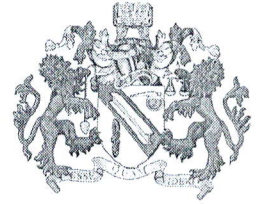
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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
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A Member of the BSI Group of Companies.

# bsi.



By Royal Charter

# 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:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 1994-08-11

Latest Revision Date: 2019-01-17

Effective Date: 2019-01-27

Expiry Date: 2022-01-26

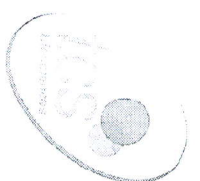


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**SELF DECLARATION OF CONFORMITY**

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

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

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

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

Signed by: Sue Brown Date: 30.04.2016

Name: Sue Brown  
Position: Regulatory Affairs Manager

Signed by: Lynda Preston Date: 30.04.2016

Name: Lynda Preston  
Position: Managing Director