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, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-08-11
Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27
Expiry Date: 2025-01-26

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Digitally signed by Monastîrschii Viorica
Date: 2023.01.24 13:31:48 EET
Reason: MoldSign Signature
Location: Moldova

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, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2013-06-10
Effective Date: 2022-01-27
Latest Revision Date: 2022-01-14
Expiry Date: 2025-01-26

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accuracy and quality as a science

tcs biosciences

Certificate of Analysis

Product Description:	Donor Horse Serum
Batch No:	31559100
Country of Origin:	United Kingdom
Process:	Sterile filtered to 0.1µm
Storage:	-15˚C or below
Expiry:	2021.11

Sterility Testing

Bacteria	Not Detected
Yeasts and Fungi	Not Detected
Mycoplasma	Not Detected
Viruses:	
Equine Infectious Anaemia	Not Detected
Equine Viral Arteritis	Not Detected

Physical and Biochemical Analysis

pH	7.39 at 22˚C
Osmolality	291 mOsmol/kg
Haemoglobin	0.179 mg/ml
Total Protein	74.92 mg/ml
Endotoxin	0.491 EU/ml
Visual check	Straw coloured frozen liquid

Functional Testing

Cell Growth (L929)	113% of control
Cell Growth (SP2)	107% of control
Plating Efficiency (L929)	120% of control

No evidence of cytotoxicity noted

All test results were obtained from samples confirmed as taken from a homogenous batch

Documentation approval — 14.08.2017

Quality Assurance – Date

Product Release — K. Beischke 14-08-2017.

Quality Control - Date

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i www.tcsbiosciences.co.uk

Registered in England No. 2172900 VAT No. 729 8545 85

SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA account number 0000009546 that the following CE marked products:

GMDN Term	GMDN Code	TCS product code and description
General microbial isolate identification control IVD	63319	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: September 2020

Name: Sue Brown
Position: Quality Assurance & Regulatory Affairs Manager

Signed by: Lynda Preston Date: September 2020

Name: Lynda Preston
Position: Managing Director

Manufacturer
TCS Biosciences Ltd
Botolph Claydon
Buckingham MK18 2LR
UK

EC Authorised Representative
TCS Biosciences Europe B.V.
Provincialeweg 6
9864 PD Kornhorn
The Netherlands

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: Ian Brown