

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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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

Latest Revision Date: 2022-01-14

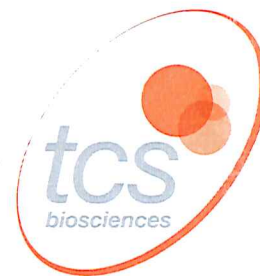
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Certificate of Analysis

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

TCS Biosciences Ltd

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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: Sue Brown