



**SELF DECLARATION OF CONFORMITY**

We declare under our sole responsibility in accordance with MHRA Registration Number IVD 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



accuracy and quality as a science



### Authorisation to Distribute

TCS Biosciences Limited, having registered offices in Botolph Claydon, Buckingham MK18 2LR, England, confirms that:

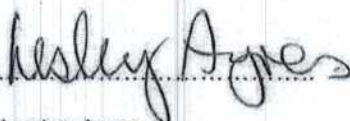
**SanMedico SRL, str. Petricani 88/1, office 10, MS-2059, mun.Chisinau, Republic of Moldova**

is authorised to promote and sell the TCS Biosciences range of products in the Republic of Moldova, on a non-exclusive basis.

SanMedico SRL is also authorised to participate in tenders, to submit quotations and to deliver these products within the territory of the Republic of Moldova.

This letter of authorisation is valid for 1 year from the date of issue but can be terminated by either party provided that a notice period of 3 months is given.

This authorisation may be extended by 1 year, by mutual agreement between TCS Biosciences Limited and SanMedico SRL.

Signed: 

Date: 15 January 2018

Name: Lesley Ayres

Title: Key Account Manager



Registered in England No. 2172900 Vat No. GB 729 8545 85

TCS Biosciences Ltd  
Botolph Claydon Buckingham  
MK18 2LR United Kingdom  
T: +44 (0)1296 714822  
F: +44 (0)1296 714806  
e: sales@tcsgroup.co.uk  
www.tcsbiosciences.co.uk





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Signed by: Sue Brown Date: 30.04.2016

Name: Sue Brown  
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Signed by: Lynda Preston Date: 30.04.2016

Name: Lynda Preston  
Position: Managing Director



**ANNEX TO SELF DECLARATION OF CONFORMITY – SELECTROL (Dated 30.04.2016)**

List of product codes and descriptions – August 2018

Product	Description
MM01-10	Enterobacter cloacae 10 Disc
MM02-10	Escherichia coli 10 Disc
MM02-25	Escherichia coli 25 Disc
MM04-10	Klebsiella pneumoniae 10 Disc
MM04-25	Klebsiella pneumoniae 25 Disc
MM05-5	Neisseria gonorrhoeae 5 Disc
MM07-10	Shigella sonnei 10 Disc
MM08-10	Legionella pneumophila serogroup 1 10d
MM09-10	Proteus vulgaris 10 Disc
MM09-25	Proteus vulgaris 25 Disc
MM10-10	Pseudomonas aeruginosa 10 Disc
MM10-25	Pseudomonas aeruginosa 25 Disc
MM100-10	Haemophilus influenzae 10 Disc
MM11-10	Salmonella Typhimurium 10 Disc
MM11-25	Salmonella Typhimurium 25 Disc
MM12-10	Serratia marcescens 10 Disc
MM13-10	Staphylococcus aureus 10 Disc
MM13-25	Staphylococcus aureus 25 Disc
MM14-10	Staphylococcus aureus 10 Disc
MM14-25	Staphylococcus aureus 25 Disc
MM15-10	Staphylococcus epidermidis 10 Disc
MM15-25	Staphylococcus epidermidis 25 Disc
MM16-10	Streptococcus agalactiae 10 Disc
MM17-10	Enterococcus faecalis 10 Disc
MM17-25	Enterococcus faecalis 25 Disc
MM18-10	Enterococcus faecalis 10 Disc
MM18-25	Enterococcus faecalis 25 Disc
MM19-10	Streptococcus pneumoniae 10 Disc
MM20-10	Streptococcus pyogenes 10 Disc
MM20-25	Streptococcus pyogenes 25 Disc
MM21-10	Bacillus cereus 10 Disc
MM24-10	Escherichia coli 10 Disc
MM24-25	Escherichia coli 25 Disc
MM26-10	Enterobacter aerogenes 10 Disc
MM26-25	Enterobacter aerogenes 25 Disc

Product	Description
MM27-10	Citrobacter freundii 10 Disc
MM28-10	Candida albicans 10 Disc
MM28-25	Candida albicans 25 Disc
MM29-10	Bacillus subtilis 10 Disc
MM29-25	Bacillus subtilis 25 Disc
MM30-10	Staphylococcus aureus 10 Disc
MM30-25	Staphylococcus aureus 25 Disc
MM31-10	Clostridium sporogenes 10 Disc
MM33-10	Escherichia coli 10 Disc
MM33-25	Escherichia coli 25 Disc
MM34-10	Escherichia coli (mcr-1) 10 Disc
MM35-10	Enterococcus hirae 10 Disc
MM36-10	Campylobacter jejuni 10 Disc
MM37-10	Haemophilus influenzae 10 Disc
MM38-10	Escherichia coli 10 Disc
MM38-25	Escherichia coli 25 Disc
MM40-25	Pseudomonas aeruginosa 25 Disc
MM41-10	Pseudomonas aeruginosa 10 Disc
MM42-10	Candida albicans 10 Disc
MM42-25	Candida albicans 25 Disc
MM43-10	Proteus mirabilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM45-10	Clostridium perfringens 10 Disc
MM46-10	Clostridium perfringens 10 Disc
MM46-10	Staphylococcus aureus 10 Disc
MM46-25	Staphylococcus aureus 25 Disc
MM47-10	Listeria monocytogenes 10 Disc
MM48-10	Listeria monocytogenes 10 Disc
MM48-25	Listeria monocytogenes 25 Disc
MM50-10	Saccharomyces cerevisiae 10 Disc
MM51-10	Enterobacter cloacae 10 Disc
MM52-10	Enterococcus faecalis 10 Disc
MM53-10	Candida krusei 10 Disc
MM54-10	Candida parapsilosis 10 Disc
MM55-10	Klebsiella pneumoniae 10 Disc
MM56-10	Klebsiella pneumoniae 10 Disc
MM57-10	Escherichia coli 10 Disc
MM58-10	Klebsiella pneumoniae 10 Disc
MM59-10	Klebsiella pneumoniae 10 Disc
MM60-10	Streptococcus dysgalactiae 10 Disc
MM62-10	Salmonella Enteritidis 10 Disc





# 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 Sys Cert Ops & Compliance Director

Original Registration Date: 1994-08-11

Latest Revision Date: 2017-07-17

Effective Date: 2016-01-27

Expiry Date: 2019-01-26

Page: 1 of 1



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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](http://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.



# 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 Sys Cert Ops & Compliance Director

Original Registration Date: 2013-06-10

Latest Revision Date: 2017-07-17

Effective Date: 2016-01-27

Expiry Date: 2019-01-26



Page: 1 of 1

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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.





For Life is Precious

# HiMedia Laboratories Pvt. Ltd.

Date: 01<sup>st</sup> December 2017

## STATEMENT

We, **HiMedia Laboratories Pvt. Ltd.**, having a registered office at A-516, Swastik Disha Business Park, Via Vadhani Industrial Estate, L.B.S. Marg, Mumbai – 400 086, INDIA, assign **SRL SANMEDICO** having a registered office at A. Corobceanu street 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.

For **HIMEDIA LABORATORIES PVT. LTD.**,

Mr. V.M. WARKE.



**DIRECTOR – SALES & MARKETING**

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.  
Tel : 00-91-22-6116 9797 / 2500 1607 | Fax : 00-91-22-2500 2286

CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.  
Tel : 00-91-22-6147 1919 / 2500 3747 | Fax : 00-91-22-6147 1920 / 2500 5764 | Email : info@himedialabs.com

Web : www.himedialabs.com

ISO 9001-2015  
CERTIFIED



... expect only quality from us™  
CIN : U85195MH1982PTC198104



**DECLARATION OF CONFORMITY**

1) Manufacturer (Name, department): HiMedia Laboratories Pvt. Ltd.  
 Address: 23 Vadhani Industrial Estate, LBS Marg, Mumbai - 86, MS, India  
 and

2) European authorized representative: CEpartner4U BV,  
 Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;  
 (on product labels printed as:  
 CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) (groupnames /):

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants, Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J. Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs	NL-CA002-2013-26445	5
CCM	Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits, Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid	NL-CA002-2013-26446	6
MBP	Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits	NL-CA002-2013-26447	7

*type and model numbers: see appendix*

4) The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):  
 Conformity assessment procedure for CE marking: In vitro Diagnostic Medical Device Directive, Annex III

Mumbai, India; 2018-30-10

(Place & date of issue (yyyy-mm-dd))

Dr. G.M. Warke, Managing Director  
 (name; function and signature of manufacturer)





# CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this qualityaustria certificate to the following organisation:

**HIMEDIA**

**HiMedia Laboratories Pvt. Ltd.**  
23, Vadhani Industrial Estate L.B.S.Marg,  
Ghatkopar (W), Mumbai - 400086, Maharashtra,  
India  
Unit-1: B-4-5-6, MIDC, Palkhed, Dindori,  
Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Differentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

The validity of the qualityaustria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

This qualityaustria certificate confirms the application and further development of an effective

**QUALITY MANAGEMENT SYSTEM**  
complying with the requirements of standard  
**EN ISO 13485:2012**  
Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00275/0

Date of initial issue: 21 November 2017

Valid until: 31 March 2019

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,  
AT-1010 Vienna, Zelinkagasse 10/3

*Scheiber*  
Konrad Scheiber  
General Manager

*Stefan*  
Ing. Andreas Aichinger, MSc  
Specialist representative



The current validity of the certificate is documented exclusively on the Internet under  
<http://www.qualityaustria.com/en/cert> EAC: 23

Doc. No. QA-Z-028  
Seit 1997/2006-4436  
#1762706604040





# CERTIFICATE

This Certificate confirms the application and further development of an effective

## WHO GMP Compliance System

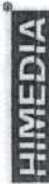
Complying with the requirement of

## WHO GMP Guidelines

Quality Austria Central Asia Private Limited  
(A Division of Peacock Global Company)  
Awards this Certificate to

### Himedia Laboratories Pvt. Ltd.

Unit I : B/4-6, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India  
Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombivli, District Thane - 421 204, Maharashtra, India  
Unit III : D-61 MIDC, Phase-II, Near Shanti Mandir, Dombivli, District Thane - 421204, Maharashtra, India



Unit I : Manufacture & supply of Biosciences products for applications in Microbiology (includes Dehydrated Culture Media, Culture Media Bases, Antimicrobial Susceptibility Systems & Bacteriological Differentiation Aids), Animal Cell Culture, Plant Tissue Culture and Molecular Biology  
Unit II : Manufacture and supply of Sterile Ready Prepared Media  
Unit III : Manufacture and supply of Sterile Ready Prepared Media

Report No.: QACA/WHO/069  
Issue Date: 21/12/2016  
Expiry Date: 20/12/2019

The Product and Systems Liability rests with the manufacturer and under no circumstances Quality Austria Central Asia Shall be Held Responsible

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

India: 20 Dec 2016  
Quality Austria Central Asia Private Limited (A division of Peacock Global company)

 **qualityaustria**  
**central asia**  
*Succeed with Quality*

  
Alok Kumar  
Country Head



The current validity of the certificate is documented exclusively on the Intranet under [www.qualityaustriacentralasia.com](http://www.qualityaustriacentralasia.com)

