

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: *Lee Brown*



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

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	Pseudomonas aeruginosa 25 Disc
MM11-10	Haemophilus influenzae 10 Disc
MM11-25	Salmonella Typhimurium 10 Disc
MM12-10	Salmonella Typhimurium 25 Disc
MM13-10	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	Staphylococcus epidermidis 10 Disc
MM17-10	Streptococcus agalactiae 10 Disc
MM17-25	Enterococcus faecalis 10 Disc
MM18-10	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	Enterococcus hirae 10 Disc
MM37-10	Campylobacter jejuni 10 Disc
MM38-10	Haemophilus influenzae 10 Disc
MM38-25	Escherichia coli 10 Disc
MM40-25	Escherichia coli 25 Disc
MM41-10	Pseudomonas aeruginosa 25 Disc
MM42-10	Pseudomonas aeruginosa 10 Disc
MM42-25	Candida albicans 10 Disc
MM43-10	Candida albicans 25 Disc
MM44-10	Proteus mirabilis 10 Disc
MM44-10	Bacteroides fragilis 10 Disc
MM45-10	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	Staphylococcus aureus 10 Disc
MM48-10	Listeria monocytogenes 10 Disc
MM48-25	Listeria monocytogenes 25 Disc
MM50-10	Listeria monocytogenes 10 Disc
MM51-10	Saccharomyces cerevisiae 10 Disc
MM52-10	Enterobacter cloacae 10 Disc
MM53-10	Enterococcus faecalis 10 Disc
MM54-10	Candida krusei 10 Disc
MM55-10	Candida parapsilosis 10 Disc
MM56-10	Klebsiella pneumoniae 10 Disc
MM57-10	Klebsiella pneumoniae 10 Disc
MM58-10	Escherichia coli 10 Disc
MM59-10	Klebsiella pneumoniae 10 Disc
MM60-10	Klebsiella pneumoniae 10 Disc
MM62-10	Streptococcus dysgalactiae 10 Disc
	Salmonella Enteritidis 10 Disc

Product	Description
MM63-10	Escherichia coli 10 Disc
MM64-10	Staphylococcus aureus 10 Disc
MM65-10	Pseudomonas aeruginosa 10 Disc
MM68-10	Proteus mirabilis 10 Disc
MM70-10	Burkholderia cepacia 10 Disc
MM73-10	Saccharomyces cerevisiae 10 Disc
MM73-25	Saccharomyces cerevisiae 25 Disc
MM75-10	Escherichia coli 10 Disc
MM76-10	Lactobacillus brevis 10 Disc
MM77-10	Listeria monocytogenes 10 Disc
MM80-10	Yersinia enterocolitica 10 Disc
MM80-25	Yersinia enterocolitica 25 Disc
MM81-10	Haemophilus influenzae 10 Disc
MM82-10	Campylobacter jejuni 10 Disc
MM83-10	Klebsiella pneumoniae 10 Disc
MM84-10	Salmonella Nottingham 10 Disc
MM85-10	Staphylococcus aureus 10 Disc
MM86-10	Bacillus cereus 10 Disc
MM86-25	Bacillus cereus 25 Disc
MM87-10	Listeria monocytogenes 10 Disc
MM88-10	Klebsiella aerogenes 10 Disc
MM89-10	Salmonella Poona 10 Disc
MM89-25	Salmonella Poona 25 Disc
MM91-10	Staphylococcus aureus 10 Disc
MM91-10	Staphylococcus aureus 10 Disc
MM92-10	Listeria innocua 10 Disc
MM93-10	Escherichia coli 0157 non-toxicogenic 10d
MM93-25	Escherichia coli 0157 non-toxicogenic 25D
MM94-10	Aspergillus brasiliensis 10 Disc
MM95-10	Streptococcus pneumoniae 10 Disc
MM97-10	Rhodococcus equi 10 Disc
MM99-10	Legionella anisa 10 Disc
MM99-10	Legionella anisa 10 Disc

Signed by: Sue Brown Date: 21.08.2018

Name: Sue Brown
Position: Regulatory Affairs Manager

Signed by: Lynda Paffon Date: 21.08.2018

Name: Lynda Paffon
Position: Managing Director

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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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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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