

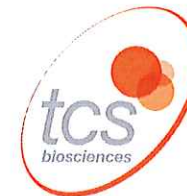
STATEMENT

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



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

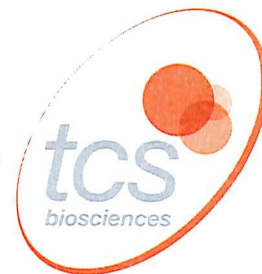
Signed by: Lynda Preston

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



Certificate of Analysis

Product Description: Donor Horse Serum
Country of Origin: United Kingdom
Batch No: 315587
Expiry: 2021.07

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	7.54
Osmolality	284 mOsmol/kg
Haemoglobin	0.212 mg/ml
Total Protein	68.95 mg/ml
Endotoxin	0.171 EU/ml
Visual check	Satisfactory

Functional Testing

Cell Growth (L929)	85% of control
Cell Growth (SP2)	102% of control
Plating Efficiency (L929)	75% of control

No evidence of cytotoxicity noted

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

Documentation approval

 21.09.2016
Quality Assurance – Date

Product Release

 23.09.2016.
Quality Control - Date

TCS Biosciences Ltd

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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



Page: 1 of 1

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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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Expiry Date: 2025-01-26



Page: 1 of 1

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accuracy and quality as a science

The background of the lower half of the image is a close-up photograph of several petri dishes containing a red agar medium. A metal pipette tip is positioned above one of the dishes, with a small droplet of liquid about to fall. The focus is sharp on the petri dish in the foreground, while the others are slightly blurred.

Selectrol®
Technical
Guide



Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as **EUCAST**, **CLSI** and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10⁶ organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.



Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly *Aspergillus niger*):

MM94 – NCPF® 2275 / ATCC® 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

Bacillus cereus:

MM21 – NCTC® 10320 / ATCC® 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 – NCTC® 7464 / ATCC® 10876 – **PHE** recommended media and ID test control organism.

Bacillus subtilis (*Bacillus subtilis* subsp. *spizizenii*):

MM29 – NCTC® 10400 / ATCC® 6633 / WDCM 00003 – used in antibiotic assays (fully sensitive), **PHE** recommended media and ID test control organism.



Bacteroides fragilis:

MM44 – NCTC® 9343 / ATCC® 25285 – type strain, **PHE** recommended strain for media and sensitivity test control.

Campylobacter jejuni (*Campylobacter jejuni* subsp. *jejuni*):

MM82 – NCTC® 11322 / ATCC® 29428 / WDCM 00156 – **PHE** recommended strain for media control.

MM36 – NCTC® 11351 / ATCC® 33560 – **EUCAST** recommended strain for susceptibility testing.

Candida albicans:

MM28 – NCPF® 3255 / ATCC® 2091 / WDCM 00055 – sensitivity control / industrial use.

MM42 – NCPF® 3179 / ATCC® 10231 / WDCM 00054 – pharmaceutical / media testing / **PHE** recommended strain for media control.

CRE ≡ 'Carbapenem Resistant Enterobacteriaceae' / CPE ≡ 'Carbapenemase Producing Enterobacteriaceae'

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem² such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – produces a Class B VIM-1 Carbapenemase.

MM56 *Klebsiella pneumoniae* – NCTC® 13443 – produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – produces a Class D OXA-48 Carbapenemase.

MM57 *Escherichia coli* – NCTC® 13476 – produces a Class B IMP Carbapenemase.

MM33 *Escherichia coli* – NCTC® 10418 / ATCC® 10536 – recommended by **PHE** as a negative control for CRE testing.

Citrobacter freundii:

MM27 – NCTC® 9750 / ATCC® 8090 – type strain.

Clostridium perfringens:

MM45 – NCTC® 8237 / ATCC® 13124 / WDCM 00007 – type strain. **PHE** recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which does not produce the lethal epsilon toxin of potential interest to bioterrorists.

Clostridium sporogenes:

MM31 – NCTC® 532 / ATCC® 19404 / WDCM 00008 – used for media control. **PHE** recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

Enterobacter aerogenes:

MM26 – NCTC® 10006 / ATCC® 13048 / WDCM 00175 – type strain; used in water, paint and adhesive testing.

Enterobacter cloacae:

MM01 – NCTC® 13380 / ATCC® 23355 / WDCM 00082 – disinfectant control, media testing.

MM51 – NCTC® 13406 – **PHE** recommended strain for QC of AmpC (de-repressed) detection.

Enterococcus faecalis:

MM52 – NCTC® 13379 / ATCC® 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows high-level resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC® 775 / ATCC® 19433 / WDCM 00009 – used in water industry and QC. **PHE** recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC® 12697 / ATCC® 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. **PHE** recommended positive control strain for aesculin test. **CLSI**, **EUCAST** recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.

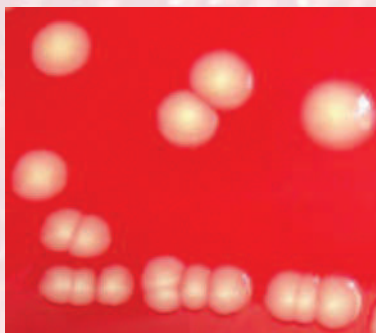


***Enterococcus hirae*:**

MM35 – NCTC® 13383 / ATCC® 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alpha-haemolytic on sheep blood agar.

***Escherichia coli* strains:**

MM02 – NCTC® 12241 / ATCC® 25922 / WDCM 00013 – **EUCAST**, **CLSI**, **PHE** recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 – NCTC® 13476 – CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC® 10418 / ATCC® 10536 – (**PHE** recommended alternative to NCTC 12241) fully sensitive control strain. **PHE** recommended positive control for indole test, ONPG test, negative control for oxidase test, **PHE** recommended negative control for CRE and ESBL testing.

MM24 – NCTC® 11954 / ATCC® 35218 – beta-lactamase positive strain. **CLSI** recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC® 9001 / ATCC® 11775 / WDCM 00090 – used in water / chemical industry. **PHE** recommended strain for media QC.

MM93 – NCTC® 12900 / ATCC® 700728 / WDCM 00014 – O157 strain (non-toxigenic). **PHE** recommended strain for media QC.

MM63 – NCTC® 11560 – beta-lactamase positive strain.

MM38 – NCTC® 12923 / ATCC® 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC® 13846 – Possesses the plasmid-mediated mcr-1 colistin resistance mechanism gene and is recommended by **PHE** and **EUCAST** as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.

***Haemophilus influenzae* strains:**

MM81 - NCTC® 12699 / ATCC® 49247 – is a 'BLNAR' strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. **PHE**, **CLSI** recommended QC strain for susceptibility testing media.

MM98 – NCTC® 11931 – a fully sensitive strain. **PHE** recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC® 8468 / ATCC® 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

MM37 – NCTC® 12975 / ATCC® 49766 – recommended by **EUCAST**.

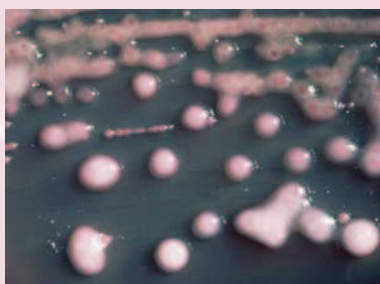


***Klebsiella* strains:**

MM04 *Klebsiella pneumoniae* – NCTC® 9633 / ATCC® 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC® 13368 / ATCC® 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 *Klebsiella pneumoniae* – NCTC® 13443 – CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes* (*Raoultella planticola*) – NCTC® 9528 – used in water / pharmaceutical industry. **PHE** recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.



Lactobacillus brevis:

MM76 – NCTC® 13386 / ATCC® 8287 – used in food industry.

***Legionella pneumophila* serogroup 1:**

MM08 – NCTC® 11192 / ATCC® 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

Listeria innocua:

MM92 – NCTC® 11288 / ATCC® 33090 / WDCM 00017 – type strain. Non-pathogenic.

Listeria monocytogenes:

MM87 – NCTC® 11994 / WDCM 00019 – type strain, **PHE** recommended positive control strain for *Listeria* detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC® 7973 / ATCC® 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC® 13372 / ATCC® 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

Neisseria gonorrhoeae:

MM96 – NCTC® 12700 / ATCC® 49226 – has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. **PHE** recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO₂ is helpful in growth.

MM05 – NCTC® 8375 / ATCC® 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. **PHE** recommended strain for media QC.

Proteus mirabilis:

MM43 – NCTC® 13376 / ATCC® 14153 – pharmaceutical / disinfectant / media control.

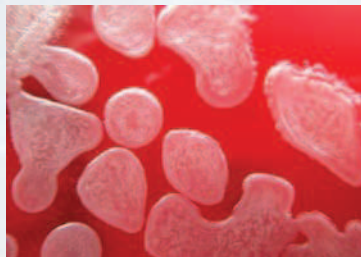
MM68 – NCTC® 10975 – media control. **PHE** recommended control for motility test.

Proteus vulgaris:

MM09 – NCTC® 4175 / ATCC® 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

***Pseudomonas aeruginosa* strains:**

MM10 – NCTC® 12903 / ATCC® 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 – NCTC® 10662 / ATCC® 25668 / WDCM 00114 – is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC® 12924 / ATCC® 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC® 13359 / ATCC® 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

Rhodococcus equi:

MM97 – NCTC® 1621 / ATCC® 6939 / WDCM 00028 – type strain.

Saccharomyces cerevisiae:

MM73 – NCPF® 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 – used for QC of culture media and for antifungal susceptibility testing.

***Salmonella* serotypes:**

MM11 *Salmonella* Typhimurium – NCTC® 12023 / ATCC® 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 *Salmonella* Poona – NCTC® 4840 – (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 *Salmonella* Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

Serratia marcescens:

MM12 – NCTC® 13382 / ATCC® 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.

Staphylococcus aureus:

(A) Fully sensitive:

MM85 – NCTC® 6571 / ATCC® 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of Staph aureus strains. Sensitive to penicillin and ceftazidime / methicillin / oxacillin. **PHE** recommended coagulase, DNase and catalase positive control.

MM13 – NCTC® 12981 / ATCC® 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all anti-staphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC® 12973 / ATCC® 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. **EUCAST**, **CLSI** strain. Sensitive to ceftazidime / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC® 7447 / ATCC® 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Ceftazidime / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (ceftazidime / methicillin / oxacillin resistant):

MM91 – NCTC® 13373 / ATCC® 43300 / WDCM 00211 (MRSA) – Possesses mecA gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level ceftazidime / oxacillin / methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of ceftazidime – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for ceftazidime.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully ceftazidime / oxacillin / methicillin sensitive strain (such as MM13). **CLSI** recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC® 12493 / WDCM 00212 (MRSA) – possesses mecA gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level ceftazidime / methicillin / oxacillin resistance. **EUCAST** recommended strain. Instances have been reported where loss of the mecA gene has occurred during storage.

D) Other:

MM46 – NCTC® 10788 / ATCC® 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.



Staphylococcus epidermidis:

MM15 – NCTC® 13360 / ATCC® 12228 / WDCM 00036 – used for media control / antibiotic assay. Colonies are small and beta-haemolytic.

Streptococcus agalactiae: (Beta-haemolytic Streptococcus group B)

MM16 – NCTC® 8181 / ATCC® 13813 – type strain, used for QC. **PHE** recommended negative control for aesculin test.

***Streptococcus pneumoniae* strains:**

MM95 – NCTC® 12977 / ATCC® 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. **PHE** recommended positive control for bile solubility test. **CLSI, EUCAST** recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC® 12695 / ATCC® 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.



Streptococcus pyogenes:

MM20 – NCTC® 12696 / ATCC® 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic. **PHE** recommended blood agar control.

Vibrio parahaemolyticus:

MM06 – NCTC® 10885 / WDCM 00185 – used for QC of media and ID testing. **PHE** recommended strain used mainly in the food industry.

Yersinia enterocolitica:

MM80 – NCTC® 12982 / ATCC® 9610 / WDCM 00038 – type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

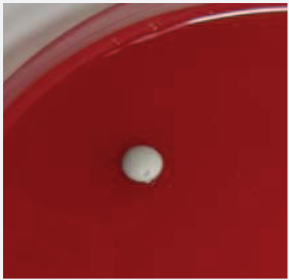
- 1 European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.
- 2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).
- 3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

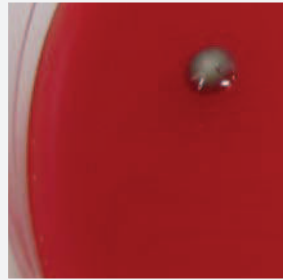
Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.



Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies



Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests



Place disc in a small volume of a suitable broth medium such as brain-heart infusion



Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium



Out-of-specification results

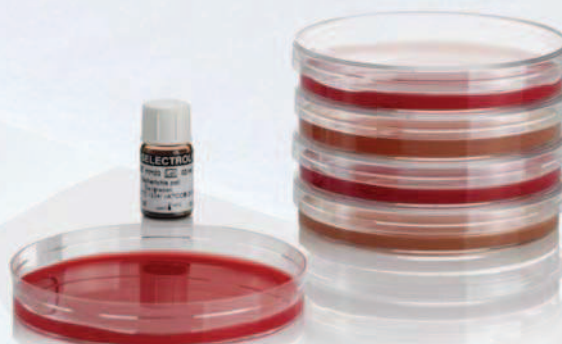
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly – check standard operating procedures
- There is an instrumentation error – check calibration, mechanical functioning, etc
- There is a problem with the consumables – out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.



Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol® disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)
- Assume the count in the broth to be 10^8 organisms per ml ----- (A)
- Mix and transfer 100 µl of (A) to 100 ml of saline or ¼ strength Ringer's solution -- (B)
- Mix and transfer 100 µl of (B) to 10 ml of saline or ¼ strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10^8 organisms per ml
- (B) contains 10^5 organisms per ml
- (C) contains 10^3 organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol® organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.





Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol® strain MM33) mentioned above is designated WDCM 00033.

***Staphylococcus aureus* WDCM 00033**

AHU 1142; **ATCC™ 6538P**; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; **NCTC 7447**; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Every effort has been made to ensure the accuracy of the information in this document, however TCS makes no warranties, expressed or implied, regarding errors or omissions and assumes no legal liability or responsibility for loss or damage resulting from the use of information contained within.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94	00053
<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21	00001
<i>Bacillus cereus</i>	NCTC [®] 7464 / ATCC [®] 10876	MM86	
<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29	00003
<i>Bacteroides fragilis</i>	NCTC [®] 9343 / ATCC [®] 25285	MM44	
<i>Campylobacter jejuni</i>	NCTC [®] 11351 / ATCC [®] 33560	MM36	
<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82	00156
<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28	00055
<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42	00054
<i>Citrobacter freundii</i>	NCTC [®] 9750 / ATCC [®] 8090	MM27	
<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45	00007
<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31	00008
<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26	00175
<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01	00082
<i>Enterobacter cloacae</i>	NCTC [®] 13406	MM51	
<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17	00009
<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18	00087
<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52	00085
<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35	00011
<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02	00013
<i>Escherichia coli</i>	NCTC [®] 11954 / ATCC [®] 35218	MM24	
<i>Escherichia coli</i>	NCTC [®] 10418 / ATCC [®] 10536	MM33	
<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38	00012
<i>Escherichia coli</i>	NCTC [®] 11560	MM63	
<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75	00090
<i>Escherichia coli</i> CRE	NCTC [®] 13476	MM57	
<i>Escherichia coli</i> (mcr-1)	NCTC [®] 13846	MM34	
<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93	00014
<i>Haemophilus influenzae</i>	NCTC [®] 8468 / ATCC [®] 9334	MM100	
<i>Haemophilus influenzae</i>	NCTC [®] 12975 / ATCC [®] 49766	MM37	
<i>Haemophilus influenzae</i>	NCTC [®] 12699 / ATCC [®] 49247	MM81	
<i>Haemophilus influenzae</i>	NCTC [®] 11931	MM98	
<i>Klebsiella aerogenes</i>	NCTC [®] 9528	MM88	
<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04	00097
<i>Klebsiella pneumoniae</i>	NCTC [®] 13368 / ATCC [®] 700603	MM83	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13440	MM55	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13443	MM56	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13442	MM59	
<i>Lactobacillus brevis</i>	NCTC [®] 13386 / ATCC [®] 8287	MM76	
<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08	00107
<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92	00017
<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48	00109
<i>Listeria monocytogenes</i>	NCTC [®] 13372 ATCC [®] 7644	MM77	
<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87	00019
<i>Neisseria gonorrhoeae</i>	NCTC [®] 8375 / ATCC [®] 19424	MM05	
<i>Neisseria gonorrhoeae</i>	NCTC [®] 12700 / ATCC [®] 49226	MM96	
<i>Proteus mirabilis</i>	NCTC [®] 13376 / ATCC [®] 14153	MM43	
<i>Proteus mirabilis</i>	NCTC [®] 10975	MM68	
<i>Proteus vulgaris</i>	NCTC [®] 4175 / ATCC [®] 13315	MM09	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10	00025
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40	00026
<i>Pseudomonas aeruginosa</i>	NCTC [®] 13359 / ATCC [®] 15442	MM41	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65	00114
<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97	00028
<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716/ ATCC [®] 9763	MM50	00058
<i>Saccharomyces cerevisiae</i>	NCPF [®] 3178	MM73	
<i>Salmonella</i> Nottingham	NCTC [®] 7832	MM84	
<i>Salmonella</i> Poona	NCTC [®] 4840	MM89	
<i>Salmonella</i> Typhimurium	NCTC [®] 12023/ ATCC [®] 14028	MM11	00031
<i>Serratia marcescens</i>	NCTC [®] 13382 / ATCC [®] 8100	MM12	
<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13	00034
<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14	00131
<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30	00033
<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46	00032
<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85	00035
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64	00212
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91	00211
<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15	00036
<i>Streptococcus agalactiae</i>	NCTC [®] 8181 / ATCC [®] 13813	MM16	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12695 / ATCC [®] 6303	MM19	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12977 / ATCC [®] 49619	MM95	
<i>Streptococcus pyogenes</i>	NCTC [®] 12696 / ATCC [®] 19615	MM20	
<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06	00185
<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21
00003	<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29
00007	<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45
00008	<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31
00009	<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17
00011	<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35
00012	<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38
00013	<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02
00014	<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93
00017	<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92
00019	<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87
00025	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10
00026	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40
00028	<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97
00031	<i>Salmonella</i> Typhimurium	NCTC [®] 12023 / ATCC [®] 14028	MM11
00032	<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46
00033	<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30
00034	<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13
00035	<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85
00036	<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15
00038	<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80
00053	<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94
00054	<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42
00055	<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28
00058	<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716 / ATCC [®] 9763	MM50
00082	<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01
00085	<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52
00087	<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18
00090	<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75
00097	<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04
00107	<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08
00109	<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48
00114	<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65
00131	<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14
00156	<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82
00175	<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26
00185	<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06
00211	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91
00212	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64

Notes





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Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
fax: +49-8773/707 80-29

TO WHOM IT MAY CONCERN

To any governmental departments,
registration and/or trade offices
in Moldova

Distribution / Service Authorisation for the years 2019 - 2023

This letter confirms that company

SANMEDICO SRL

Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldava MD-2059
MOLDOVA
Phone: 00373-22-623032
Email: sanmedico.office@gmail.com

is the **authorized, exclusive and sole** representative of **TECO Medical Instruments, Production + Trading GmbH, Dieselstrasse 1, 84088 Neufahrn i.NB, Germany**, for the territory of **Moldova**, only for all TECO products listed below. **Sanmedico** may participate in public and privat tenders, providing sales to all TECO customers in the territory. We as manufacturer, certify that our **warranty and service** is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules, and the specifications of the published literature, catalogues and fully covering the commodities offered.

Validity:

August 20th, 2019 to December 31st, 2023

Termination:

Confirmation ends automatically on Dec. 31st of 2023
and must be then renewed.

TECO products:

- Coatron X (Eco, Pro, Top) new manual Coagulometers (1, 2 and 4 channel)
- Coatron A4, A6, A6 Plus Fully automated Coagulometers (4 and 6 channel)
- Complete line of Hemostasis Reagents, Consumables and Spareparts

This document is signed in Neufahrn, Germany, on August 20th, 2019.

TECO Medical Instruments, Production + Trading GmbH



MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH
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Christian Hoetzl
General Manager

TECO

MEDICAL INSTRUMENTS
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Neufahrn, 26/04/2018

TO WHOM IT MAY CONCERN

We confirm that the instruments Coatron X Eco, Coatron X Pro and Coatron X Top have a closed cuvette system. Cuvettes have to be purchased with voucher identification code from TECO GmbH.



Christian Hoetzl
General Manager
TECO Germany



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#100/07-2021

Wir / We

TECO Medical Instruments Production and Trading GmbH

Name des Herstellers / Manufacturer's name
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / Address

erklären in alleiniger Verantwortung, dass die unten gelisteten IVD Zubehör Produkte:
declare under our own responsibility, that the IVD accessories products, listed below:

Doppelküvette / <i>Double cuvette</i>	Ref. 19 000 02
Einzelküvette / <i>Single cuvette</i>	Ref. 20 000 02, 24 100 00
4-fach Küvette / <i>Cuvette 4 pos/ea</i>	Ref. 80 521 10
6-fach Küvette / <i>Cuvette 6 pos/ea</i>	Ref. 80 560 00
6-fach Küvette (micro) / <i>Cuvette 6 pos/ea (micro)</i>	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen: *meet all applicable requirements of:*

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to article 1.

2. Richtlinie 2011/65/EU (RoHS III)

2. Directive 2011/65/EU (RoHS III)

Das QM-System des Herstellers ist zertifiziert nach:

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

EN ISO 13485:2016

Konformitätsbewertungsverfahren gemäß:

Conformity assessment procedure according to:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 27.07.2021
Neufahrn, July 27, 2021

Matthias Dieckmann
General Manager





Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1

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fon: +49-8773/707 80-0

fax: +49-8773/707 80-29

CERTIFICATE

for: **Mr. Vitalie Goreacii**

Company: **Sanmedico SRL**
Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldova MD-2059
MOLDOVA

have participated with success at the intensive training session:

Application and technical training for following instruments:

- **Coatron X series**
 - **Installation**
 - **Application**
 - **General use, also in combination with TECAM Software**
 - **Technical and After Sales Service**

Supervisors: **Mr. Chr. Hoetzi and Mrs. Wendy Guo**

Place of Training: **TECO – Germany**

Date: **November 18th, 2019**


Christian Hoetzi
General Manager



KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#200/08-2022

Hersteller / Manufacturer:

**TECO Medical Instruments
Production + Trading GmbH**

Adresse / Address:

Dieselstrasse 1, 84088 Neufahrn, Germany

Marktakteur / Actor ID SRN:

DE-MF-000022642 <https://ec.europa.eu>

Wir erklären hier für die im Anhang A (Seite 2 – 23 IVD Produkte) spezifizierten Produkte dass sie gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind als allgemeine IVD.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers i.V.m. Artikel 110 Abs.3 und Abs.4 der Verordnung (EU) 2017/746 und des § 8 Abs.1 des Medizinprodukte-Durchführungsgesetzes, in der jeweils geltenden Fassung, ausgestellt.

Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

We declare herewith for the products specified in Annex A (page 2 - 23 IVD products) that they are classified as general IVD according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of the manufacturer in according to article 110 para.3 and para.4 of Regulation (EU) 217/746 and section 8 para.1 of the Medical Device Law Implementing Act.

In case of unauthorised modifications to the products or un-intended use, this declaration loses its validity.

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:

They meet applicable requirements of:

Richtlinie 98/79/EG über In-vitro-Diagnostika
klassifiziert gemäß Artikel 9 als "alle anderen Produkte"

Directive 98/79/EC on in-vitro-diagnostic medical devices
classified according to article 9 as „all other products“

Die Qualitätssicherung entspricht den Anforderungen der
Richtlinie 98/79/EG über In-vitro-Diagnostika
für diese Art von Produkten.

The Quality Assurance is in accordance with the requirements
of Directive 98/79/EC on in-vitro-diagnostic medical devices
for those kind of products.

Der implementierte QM-Prozess entspricht der EN ISO 13485:2021

The implemented QM Process complies with EN ISO 13485:2021

Die vorstehende Konformitätserklärung ist gültig für alle Chargen
dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr
gebracht wurden.

The above mentioned declaration of conformity is valid for all lots
of this product, which are distributed after the date of signature.

Das Konformitätsbewertungsverfahren entspricht Anhang III
der Richtlinie 98/79/EG über In-vitro-Diagnostika
für diese Art von Produkten.

The conformity assessment procedure complies with Annex III
of Directive 98/79/EC on in-vitro-diagnostic medical devices
for those kind of products.

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 2022-08-31


Christian Hötzi
Verantwortliche Person / PRRC

Doc#200/08-2022

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A

Übrige Produkte – Reagenzien für In-vitro-Diagnostika

Other products – Reagents for in vitro diagnostic – general IVD

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code EUDAMED DI
1	A0230-040	TEClot PT-S (Quick)	10x4ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-040X7
2	A0230-100	TEClot PT-S (Quick)	10x10ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-100WY
3	A0260-050	TEClot PT-B (Owren)	5x10ml PT-B	Prothrombin time (quick test)	W0103020199 / 55986 B-PTB-A0260-050G2
4	A0320-050	TEClot APTT-S	10x5ml APTT-S	Activated partial thromboplastin time	W0103020102 / 55982 B-APTT-A0320-050AM
5	A0401-020	TEClot TT	10x2ml TT	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
6	A0511-020	TEClot FIB	10x2ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
7	A0511-050	TEClot FIB	10x5ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
8	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
9	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
10	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
11	P8001-010	TECal N	10x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
12	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
13	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
14	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
15	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
16	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
17	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
18	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
19	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
20	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
21	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
22	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
23	P5701-010	TEClot Factor XII	10x1ml	Coagulation factor xii	W0103020211 / 30552 B-FAC-XII-P5701-010CJ

(Recital 23 of Directive 98/79/EC on In Vitro Diagnostics Medical Devices) - Annex A - general IVD

TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
fax: +49-8773/707 80-29

TO WHOM IT MAY CONCERN

To any governmental departments,
registration and/or trade offices in MOLDOVA

Distribution Authorisation Letter

This letter confirms that

Sanmedico
Mun. Chisinau
Str. Petricani 88/1 of. 10
Republica MOLDOVA

is the **legal, exclusive and sole** representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn NB, Germany**, for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may participate in public and private tenders, providing sales to all TECO customers in the territory. We as manufacturer certify that our warranty is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules and the specifications of the published literature, catalogues and fully covering the commodities offered.

Sanmedico will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:

Reporting of incidents to TECO must take place within 3 working days

Serial number of the device, exact location of the device and the user.

Validity:

January 1st, 2023 to December 31st, 2024

Termination:

Confirmation ends automatically on Dec. 31st of 2024
and must be then renewed.

Products:

- | | |
|--|---|
| • Coatron M1 | Semi-automated 1-channel Coagulometer (out of production) |
| • Coatron M2 | Semi-automated 2-channel Coagulometer (out of production) |
| • Coatron X Eco | Semi-automated 1-channel Coagulometer |
| • Coatron X Pro | Semi-automated 2-channel Coagulometer |
| • Coatron X Top | Semi-automated 4-channel Coagulometer |
| • Coatron A4 | Fully automated Coagulometer, 4 optic channels |
| • Coatron A6 | Fully automated Coagulometer, 6 optic channels |
| • Coatron A6 plus | Fully automated Coagulometer, 6 optic channels |
| all instruments with complete accessory, consumables and spare parts | |
| • Hemostasis Reagents | Complete product line |

This document is signed in Neufahrn, Germany, on January 18th, 2023

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl



Zertifikat

Hiermit wird bescheinigt, dass das Managementsystem von:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Deutschland

durch LRQA geprüft und bewertet wurde und den folgenden Normen entspricht:

ISO 13485:2016

Gültigkeits-Nr.: ISO 13485 – 00038268

Das Managementsystem ist anwendbar für:

Konstruktion, Entwicklung, Herstellung, Lagerung und Vertrieb von Gerinnungsmessgeräten und in-vitro Diagnostik Reagenzien aus den Bereichen der Hämostaseologie und Koagulation.



Paul Graaf

Area Operations Manager, Europe

Ausgestellt von: LRQA Limited



0001

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.

Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

DECLARATION OF CONFORMITY

Declaration of Conformity

Document ref.: D○C2015

Page: 1 of 6

1) Manufacturer (Name, department): "Technology-Standard" Ltd

Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia 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) **Pr○dUCT(s)** (name, type or model/batch number, etc.):

- K i t s and reagents for in vitro diagnostics of haemostasis system see *appendix*

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

Title	Document No.
<i>In vitro</i> 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

Registration nr. : **NL-CA002-2015-34420**

Barnaul, Russia; 2015-03-17

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

Andrey Momot, Director "Technology-Standard" Ltd

(name; function and signature of manufacturer)



Declaration form: Standard ISO/IEC 17050-1:2010

vs. 2011-x

Appendix

Date: 2015-02-09

Declaration of Conformity

List of devices.

Device name	Type/ model/ref number	Risk class	Code:EDMS/GMDN 1	First date of CE-compliance
«Techplastin-test» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140, 735	Low	13 02 01 01/ 30539	09.02.2015
«SFMC-test» The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma	081, 007	Low	13 02 03 03/ 43421	09.02.2015
«APTT-test» The kit of reagents for the determination of activated partial thromboplastin time	152, 001	Low	13 02 01 02/ 32392	09.02.2015
«Tech-Fib rinogen-test» The kit of reagents for the determination of fibrinogen concentration in blood plasma	324, 094, 225	Low	13 02 02 01/ 30541	09,02.2015
«ChromoTech-Plasminogen» The kit of reagents for the determination of plasminogen concentration in blood plasma	092	Low	13 02 05 05/ 30578	09.02.2015

See EDMS codes: <http://www.edma-ivd.be/> (products classification)/Preference GMDN code



Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN 1	First date of CE-compliance
«ChromoTech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Calibrtaor universal» The kit of control blood plasma for the study of haemostasis	773	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII- test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-EI-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN 1	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	774	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» Pathologic plasma	775	Low	13 02 50 02/ 32394	09.02.2015
«Techplastin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	144	Low	13 02 01 01/ 30539	09.02.2015
<(Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of Xlla-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN 1	First date of CE-compliance
«MultiTech-Fibrinogen» The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers	711, 712	Low	13 02 02 01/ 30541	09.02.2015
«Fibrinogen-Calibrator» The kit of calibrators for the determination of fibrinogen concentration	714	Low	13 02 50 02/ 39413	09.02.2015
«ADP» The kit of reagents for the determination of ADP-aggregation of platelets	030	Low	13 02 04 01/ 30569	09.02.2015
Ristomycin The kit of reagents for the determination of ristomycin-aggregation of platelets	197	Low	13 02 04 01/ 30569	09.02.2015
«Collagen» The kit of reagents for the determination of collagen-aggregation of platelets	095	Low	13 02 04 01/ 30569	09.02.2015
«Adrenaline» The kit of reagents for the determination of adrenaline- aggregation of platelets	031	Low	13 02 04 01/ 30569	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN 1	First date of CE compliance
«Aggrescreen-test» The kit of reagents for the express assessment of platelet haemostasis	010	Low	13 02 04 01/ 30569	09.02.2015
«Human platelets»	132	Low	13 02 04 01/ 32409	09.02.2015
«Sodium citrate» A reagent for the stabilization of blood in the study of haemostasis	028	Low	13 02 80 02/ 0	09.02.2015

CERTIFICATE

No. 71191



This is to certify the Quality Management System of Medical Devices of

**«Technology-Standard» LTD**

116/95, Kalinin Prospekt
656037 City of Barnaul
Russia

has been assessed and found to be in compliance with the Standard

EN ISO 13485:2016

applicable to

**Development, production and sales of diagnostic
kits and reagents for in vitro diagnostics of
hemostasis system.**

The certificate has been issued under No. **71191** for the registration
period from 05 August 2019 to 04 August 2022.
The first certificate date of issue is 05 August 2016.


Approved by


Printed by



validity code **658F2782-225**

Check the validity of this certificate using this code at www.ll-c.info

СЕРТИФИКАТ

№ 71191

Настоящий сертификат удостоверяет, что Система менеджмента качества
медицинского оборудования в



ООО фирма
«Технология-Стандарт»
проспект Калинина, 116/95
656037 г. Барнаул
Россия

была проверена и признана соответствующей требованиям стандарта

EN ISO 13485:2016

Для следующей области сертификации:

**Разработка, производство и реализация
диагностических наборов и реагентов для in vitro
диагностики системы гемостаза.**

Данный сертификат был выдан под номером **71191** и действует с
5 августа 2019 г. по 4 августа 2022 г.
Дата выдачи первого сертификата 5 августа 2016 г.


Подтвержден
Выдан

Код действительности **658F2782-225**

С помощью этого кода проверьте действительность сертификата на сайте www.ll-c.info

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Technology-Standard Ltd
116/95, Kalinin Prospekt,
Barnaul, 656037
Russia

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices were registered under number:

Group : Kits and reagents for in vitro diagnostics of haemostasis system

Notification No.: NL-CA002-2015-34420

see appendix

with Dutch Competent Authorities as a consequently these IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2016-08-19



Olga Teirlinck
Consultant CEpartner4U BV

ce partner 4 U

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