SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

# DICHIARAZIONE DI CONFORMITA'
## *Conformity declaration*

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
*The undersigned, Rinaldo Ruggero legal representative of the company:*

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo R. & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea
*or representing the authorized mandatary within the European Community*

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

| | |
|---|---|
| Denominazione/*Description* | **Padella per ammalati, urinali uomo e donna, speculum vaginali, tamponcini cotonati, tamponi sterili in provetta, tamponi sterili con terreno Amies e Stuart in provetta/ *Bed pan, Urinal's man and woman, Vaginal speculum, Cotton swab, Sterile swab in test tube, Sterile swab with medium Amies or Stuart in test tube*** |
| Materiale/*Material* | **Polipropilene, Polietilene, Legno/ *Polypropylene, Polyethylene, Wood*** |

È conforme alle disposizioni della direttiva 93/42/CE e smi, concernente i dispositivi medici ed al Decreto Legislativo di recepimento con D.lgs. del 24/02/1997 n° 46/97 e soddisfa a tutti i requisiti specificati.
Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /*It meets the EC Directive 93/42 about Medical Device, specifications established by the Italian law n 46/97, dated 24th February 1997. The device was classified as belonging to the 1st class, according to the specifications of the established by the art.9, IX enclosure of the above mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07.01.2016
Issued on January 7th 2016

SYNTESYS S.A.S.
Il legale rappresentante
Rinaldo Ruggero

Digitally signed by Monastîrschii Viorica
Date: 2023.06.09 16:35:11 EEST
Reason: MoldSign Signature
Location: Moldova

SYNTESYS

ISO9001:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
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# DICHIARAZIONE DI CONFORMITA'
## *Conformity declaration*

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
*The undersigned, Rinaldo Ruggero legal representative of the company:*

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

*O rappresentante il mandatario autorizzato entro la Unione Europea* or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

| | |
|---|---|
| Denominazione degli articoli prodotti/*Description of Manufacturer* | **Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urine.**<br><br>***Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm & 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.*** |

SYNTESYS

ISO9001:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
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COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

| | |
|---|---|
| Materiale/*Material* | **Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato**<br><br>***Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate*** |

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnotic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

SYNTESYS®

Cert. N.7111/3 Cert. N.6574/3

**SYNTESYS S.R.L.** UNIPERSONALE
VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

**DICHIARAZIONE DI CONFORMITA' UE**
***EU Declaration of conformity***

CE

**Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:**
***The undersigned, Rinaldo Ruggero legal representative of the company:***

fabbricante/*manufacturer*

**SYNTESYS S.r.l.**

indirizzo/*address*

**Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY**

**O rappresentante il mandatario autorizzato entro la Unione Europea**
***or representing the authorized mandatary within the European Community***

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

| | |
|---|---|
| Denominazione/*Description* | **Piastre di Petri in polistirolo Ø 90 mm ventilate** / *Polystyrene Petri dish Ø 90 mm h. 16 mm with vents* |
| Codice/*Code* | **318244** |
| Lotto/Lot | **182V23-04** Data di scadenza/Expiry date **03.2028** |
| Classe di rischio / Risk class | **Classe A** / *Class A* |
| Numero di registrazione unico (SRN) / Unique registration number (SRN) | **IT-MF-000027856** |
| UDI-DI di base / Basic UDI-DI | **805414149PETRICB** |

È conforme secondo il Regolamento (UE) 2017/746 concernente i Dispositivi Medico-Diagnostici in vitro e soddisfa tutti i requisiti specificati. Il dispositivo è stato classificato appartenente alla Classe A secondo la Regola 5 dell'Allegato VIII /
It complies with the Regulation (EU) 2017/746 concerning In Vitro Diagnostic Medical Devices and meets all the specified requirements. The device has been classified as belonging to Class A according to Rule 5 of Annex VIII.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà messa a disposizione delle autorità competenti secondo quanto prescritto dall'Art. 10 punto 7 del Regolamento. / *It also declares that the technical documentation supporting this declaration of conformity is kept at the company offices and will be made available to the competent authorities in accordance with the provisions of Art. 10 point 7 of the Regulations.*

Teolo (PD), 04.04.2023

SYNTESYS S.R.L.
UNIPERSONALE
Il Legale Rappresentante
Rinaldo Ruggero

SYNTESYS

Cert. N.7111/2 Cert. N.6574/2

SYNTESYS S.R.L. UNIPERSONALE
VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

# AUTHORIZATION LETTER

We, **Syntesys S.R.L.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

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.

This letter is valid till 31.12.2021

Teolo, 05.01.2021

SYNTESYS S.R.L.
UNIPERSONALE
Via G. Galilei, 10/3 - 35037 Z.I. Selve - Teolo (PD)
C.F./P.I./R.I. PD: 03573950288 - Cap. Soc. 20.700,00 €
Tel. 049 9903866 - Fax 049 9903867

Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.R.L.

IQNET

Building trust together.

# Certificate

**CISQ/ICIM S.P.A.** has issued an IQNet recognized certificate that the organization:

## SYNTESYS S.R.L.

**Head Office and Operative Unit**

**Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)**

**Operative Units**

**Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)**

**Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)**
**Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)**

has implemented and maintains a/an

**Quality Management System**

for the following scope:

**Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.**

which fulfils the requirements of the following standard:

**ISO 9001:2015**

| | |
|---|---|
| Issued on: | **2022-06-05** |
| First issued on: | **2013-06-05** |
| Expires on: | **2025-06-04** |

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-83562**

**Alex Stoichitoiu**
President of IQNET

**Mario Romersi**
President of CISQ

CISQ

IQNET

Building trust together.

# Certificate

**CISQ/ICIM S.P.A.** has issued an IQNet recognized certificate that the organization:

## SYNTESYS S.R.L.

**Head Office and Operative Unit**

**Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)**

**Operative Units**

**Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)**

**Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)**
**Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)**

has implemented and maintains a/an

**Quality Management System**

for the following scope:

**Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.**

which fulfils the requirements of the following standard:

## ISO 13485:2016

| | |
|---|---|
| Issued on: | **2022-06-05** |
| First issued on: | **2014-06-21** |
| Expires on: | **2025-06-04** |

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-93779**

**Alex Stoichitoiu**
President of IQNET

**Mario Romersi**
President of CISQ

CISQ

# 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



...making excellence a habit.™

# Certificate of Registration

## ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TCS Biosciences Ltd
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number: EMS 590359

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

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

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

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



...making excellence a habit.™

## 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

accuracy and quality as a science

tcs biosciences

# 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 $10^6$ 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.

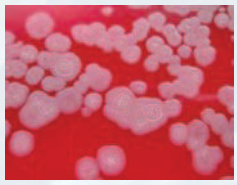
***Bacillus cereus*:**

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 carbapenem[2] 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.

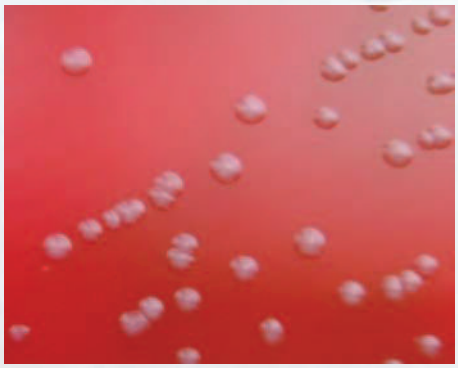
MM51– NCTC® 13406 – PHE recommended strain for QC of AmpC (de-repressed) detection.

***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.

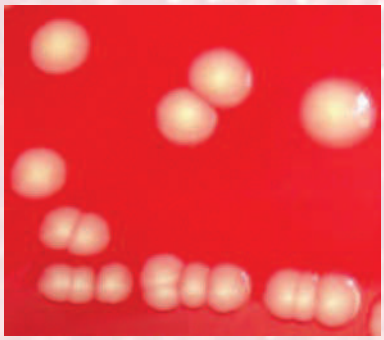


***Enterococcus hirae*:**

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.

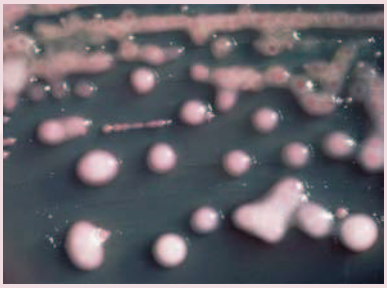
MM37 – NCTC® 12975 / ATCC® 49766 – recommended by EUCAST.

***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 $CO_2$ 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.

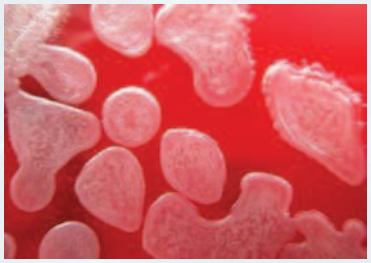
MM68 – NCTC® 10975 – media control. PHE recommended control for motility test.

***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 cefoxitin / 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 cefoxitin / 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. Cefoxitin / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (cefoxitin / 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 cefoxitin /oxacillin/methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of cefoxitin – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for cefoxitin.); 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 cefoxitin / 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 cefoxitin / 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).

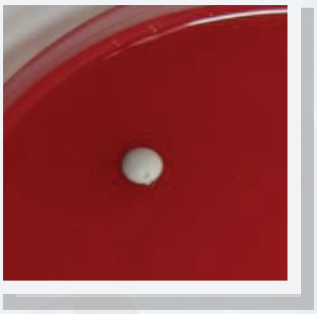
3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

# How to use Selectrol®

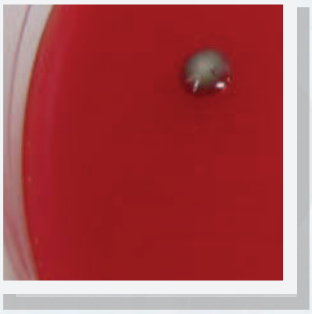
Always warm the vial to ambient temperature before opening.

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.

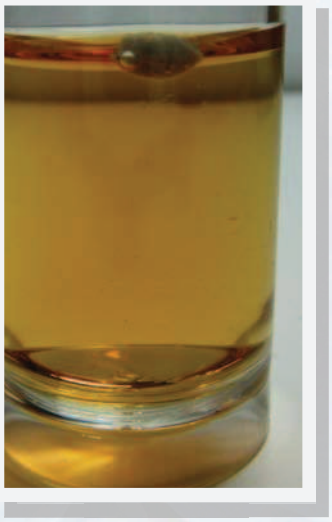


Place disc on suitable growth medium such as blood agar



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

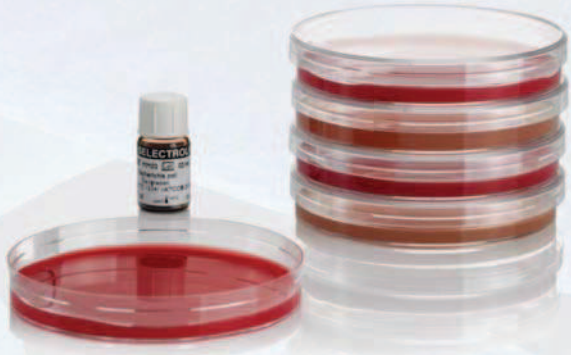
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification 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.

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# Selectrol Strain Index

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

# Selectrol Strain Index

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

# Selectrol Strains Listed by WDCM Number

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

# Notes

tcs biosciences

www.tcsbiosciences.co.uk

TCS Biosciences Ltd
Botolph Claydon, Buckingham, MK18 2LR, United Kingdom
t: +44 (0) 1296 714222, f: +44 (0) 1296 714806, e: sales@tcsgroup.co.uk

# STATEMENT

We, TCS Biosciences Ltd., having a registered office at Botolph Claydon, Buckingham, MK 18 2LR, England assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova, as Authorized Representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date : 21 August 2018

Signature: Ian Brown

ISO 9001:2008 DEKRA Certification DEKRA certified

Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008

Quality Management EN ISO 13485 www.dekra-usa.com DEKRA certified

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 / 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

TECO MEDICAL INSTRUMENTS PRODUCTION+TRADING GMBH Dieselstraße 1 D-84088 Neufahrn N.B. fon: +49-8773/70780-0

Christian Hoetzl
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

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC



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Fon +49 8773 70780 00 • Fax +49 8773 70780 29 • info@teco-gmbh.com • www.teco-medical.com

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-APTTS-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



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Fon +49 8773 70780 00 • Fax +49 8773 70780 29 • info@teco-gmbh.com • www.teco-medical.com

# 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 / *Double cuvette* | Ref. 19 000 02 |
| Einzelküvette / *Single cuvette* | Ref. 20 000 02, 24 100 00 |
| 4-fach Küvette / *Cuvette 4 pos/ea* | Ref. 80 521 10 |
| 6-fach Küvette / *Cuvette 6 pos/ea* | Ref. 80 560 00 |
| 6-fach Küvette (micro) / *Cuvette 6 pos/ea (micro)* | 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 artivel 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

Medical Instruments TECO Production+Trading GmbH

Matthias Dieckmann
General Manager

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

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.

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

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

Medical Instruments TECO Production+Trading GmbH

Certificate -Bescheinigung

**TECO** **Medical Instruments Production+Trading GmbH**
web: www.teco-gmbh.com
mail: info@teco-gmbh.com

**Dieselstrasse 1**
**D-84088 Neufahrn/NB**
fon: +49 8773 70780 00
fax: +49 8773 70780 29

# CERTIFICATE OF TRAINING

**Luminita Padurar**
Bioengineer
Sanmedico
Chisinau
Republic of Moldava

**have participated with success at the training session supervised by TECO GmbH, Germany for following instruments:**

**Coatron A series**

- **Installation**
- **Application**
- **General use, also in combination with TECAM**
- **Maintenance**
- **Troubleshooting**
- **After Sales Service**

Training details:

| | |
|---|---|
| Supervisor: | Chr. Baumgartner, Director RD of TECO |
| Device | Coatron A4 + A6, Inhouse Master Device |
| Place: | Laboratories of TECO |
| Date: | May 5th 2023 |

TECO
Dipl.-Ing. Univ.
Christian Baumgartner

Dipl.-Ing. Univ. (TUM)
**Christian Baumgartner**
Director R&D

| | | |
|---|---|---|
| Bestehendes Zertifikat: | 10 November 2022 | Erstmalige Zulassung: |
| Dieses Zertifikat ist gültig bis: | 9 November 2025 | ISO 13485 - 10 November 2022 |
| Zertifikat-Nr.: | 10479696 | |

# 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 Gerinnungsmessgerätenund in-vitro Diagnostik Reagenzien aus den Bereichen der Hämostaseologie und Koagulation.

**Paul Graaf**

Area Operations Manager, Europe

Ausgestellt von: LRQA Limited

UKAS MANAGEMENT SYSTEMS
0001

TOP
INNOVATION
2017 - 2018

Clotting
Chromogenic
Immunturbidimetric

# Coatron X

## Semi-automated
## Coagulation Analyzer Series

**With 1, 2 or 4 optical channels**


TECO
Innovation in Coagulation

# A new area of manual and semi-automated Coagulation Analyser rise up

The Coatron X instrument line is a consequent continuation in the development of the Coatron product line. Over 25 years in experience and innovation is the reference for our new Coatron X instrumentation line.
The unique detection principle in combination with the high-level analytical algorithm calculates exact, precise and reproducible results.
Easy in operation – self instructing user dialogue - reliable

**Highest optical resolution, enlarged optic range, smallest sample and reagent volume**
0.1 mOD, 0 - 3800 mOD, just with 75 µL sample and reagent volume
**Complete optical analysis**
No further parts required, like balls, stirrers etc.
**Adaptation of the light level**
Automatic light level adjustment of the optic channels to each sample
**Exclusion of disturbance**
Stray light reduction, exact temperature control, all parameter are preset

TECO

Innovation in Coagulation

“Complete range of Coagulation Analysis with the highest standard and reliability. The new generation of Coagulation instruments with optical detection are here.”

**Coatron X - product family**


With 1, 2 or 4 optical channels.

www.teco-medical.com

Coatron X

# Prepared for the daily routine and the upcoming requirements

**One instrument – many possibilities**

The Coatron X family is prepared to work with one, two or four channels. The built-up and functionality is specifically designed to each instrument version and requirements. The operation with the intuitive user dialogue and handling of the detection results are easy and effective. The possibility to connect the instrument to the **TECO Cloud** offers new perspective of instrument, reagent and consumables verification and handling. The precise and correct patient result is what we want to secure.

MADE IN GERMANY

**Quality is our basic demand**

TECO develop and produce with qualified and specialized companies, located in Germany. High reliability, nearly maintenance free instruments are our benefit. Our reference is 25 years, in worldwide laboratories, with satisfied users.

TECO CLOUD

**TECO Cloud Services – A strong data bank and application service behind**

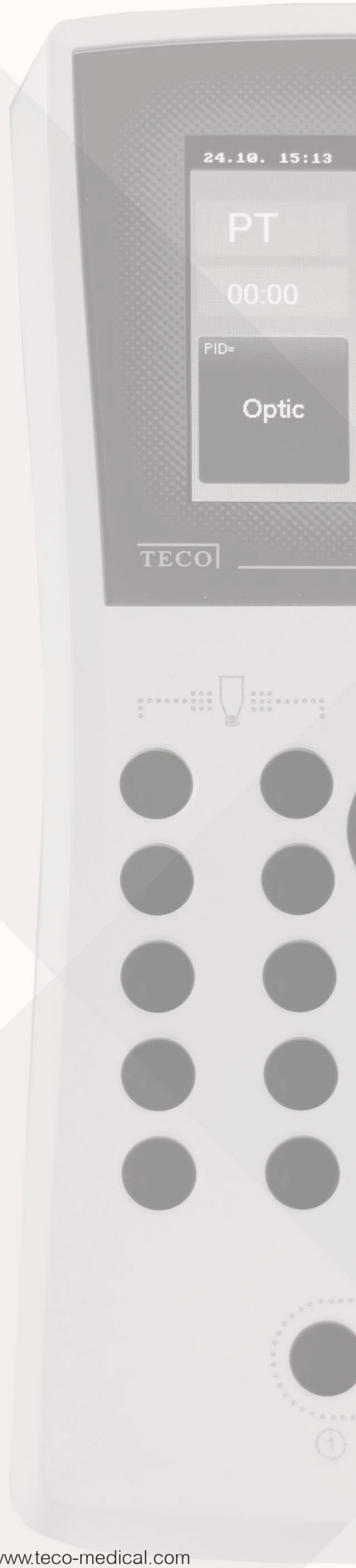
All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.


| Coatron | Eco | Pro | Top |
|---|---|---|---|
| General | | | |
| Dimensions | 230 x 148 x 94 mm (l, b, h) | | |
| Display | Colored touch display 4.3" | | |
| Pre-warm temperature | 37°C | | |
| Pre-warm cuvettes (pcs.) | 10 | 20 | 20 |
| Pre-warm reagent 24mm (pcs.) | 1 | 1 | 1 |
| Pre-warm reagent 22mm (pcs.) | 2 | 2 | 2 |
| Pre-warm reagent 11mm (pcs.) | 2 | 2 | 2 |
| Reagent mixing position | - | 1 | 1 |
| Power values | 110-240Vac, 50-60Hz / 5Vdc, 3.3A | | |
| Interfaces | | | |
| RS232 (2x) | Printer, Barcode reader | | |
| USB (2x) | Network, Firmware update | | |
| Bluetooth | TECO Cloud, App | | |
| Optic / tests | | | |
| Optic channels | 1 | 2 | 4 |
| Wavelength (nm) | 620 (red) | 405 (UV) | 405 (UV) |
| Global Coag. tests | PT, APTT, TT, FIB | | |
| Specific Coag. tests | - | individual factors | |
| Chromogenic Coag. tests | - | AT, PC | |
| Latex based tests | D-Dimer | | |
| Whole blood tests | PT-B | - | |

CE IVD

Coatron X

# The details make the difference




**Coatron X**

The remarkable details in every single component is achieved by selecting of premium suppliers.

The performance of a high level instrument is strongly depending on the concept in general and the perfect usability to reach the requirements of a modern laboratory analyser.

Priority No. 1 was to get a daily routine reliability and easy-to-use operation.

**Software and connection possibilities**

With the Coatron X product family starts a new time line in analysis management and service maintenance. Operation via intuitive, colored touchscreen, as well patient result management are perfectly optimized.

# Operation details

| Coatron | Eco | Pro | Top |
|---|---|---|---|
| Operation | | | |
| Touchscreen 4.3" | ✔ | ✔ | ✔ |
| Real time clock | ✔ | ✔ | ✔ |
| Stopwatch | ✔ | ✔ | ✔ |
| Language selection | ✔ | ✔ | ✔ |
| Interfaces | | | |
| USB to LIS | ✔ | ✔ | ✔ |
| Network to LIS (TECAM software required) | ✔ | ✔ | ✔ |
| Management | | | |
| Test calibration | ✔ | ✔ | ✔ |
| Tracking to Pat.ID, Patient ID, Sample ID or Auto ID | ✔ | ✔ | ✔ |
| Automatic optic start (no Starterpipette required) | ✔ | ✔ | ✔ |
| Double determination | ✖ | ✔ | ✔ |
| Sample management (ID) | ✖ | ✔ | ✔ |
| Reagent management (ID) (lot und expiry) | ✖ | ✔ | ✔ |
| Internal result databank | ✖ | ✔ | ✔ |
| Patient identification with barcode | | optional | |


**Intuitive operation and control**

Clear and easy to operate user dialogue with a high quality colored touchscreen

- Direct usable
- Short learning phase
- Logic, intuitive operation
- Reliable touchscreen surface
- Quick touch response


**For small and mediate laboratory requirements**

Concept is suitable for daily routine work in Coagulation laboratories and hospitals

- Three different versions available, depending on number of samples per day
- In maximum up to 4 optic channels available

**Interfaces**

**RS232 (2x)**

- For external serial printer and external barcodereader

**LIS/USB**

**Bluetooth**


Integrated barcode scan for reagents.

TECO CLOUD

**TECO Cloud Services**

**A strong data bank and application service behind**

All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.

For trading partners worldwide, please visit our web-page

**TECO Medical Instruments Production + Trading GmbH**
Dieselstr. 1, 84088 Neufahrn, Germany
Tel.: +49 (0) 8773 70780-0, Fax +49 (0) 8773 70780-29
info@teco-gmbh.com, www.teco-medical.com

TECO
Innovation in Coagulation

CoatronX-E-v0E