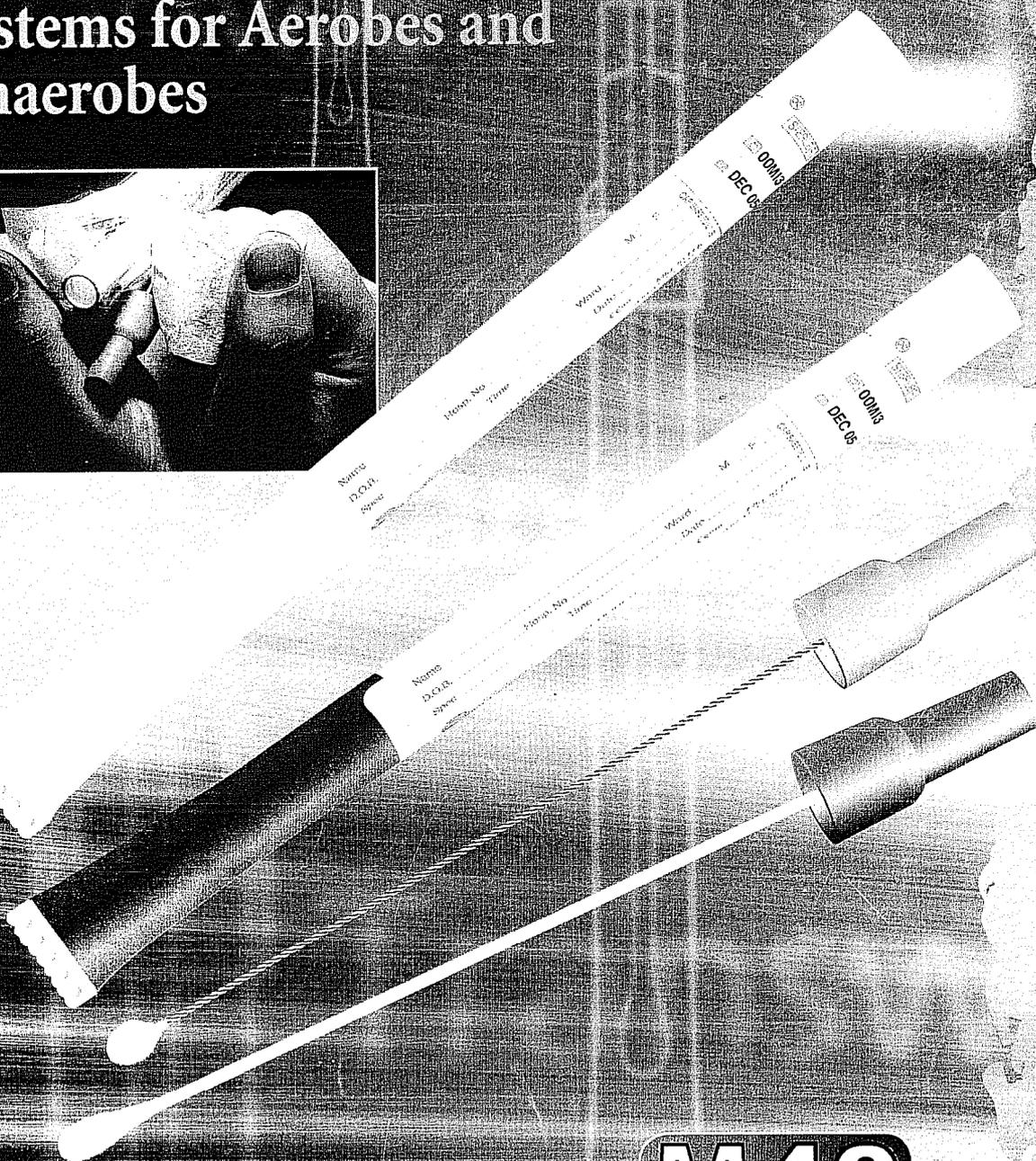
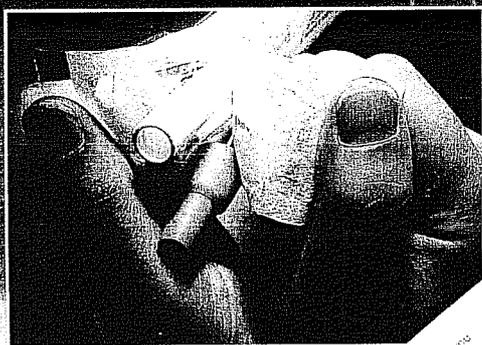




# MW&E

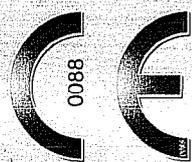
## World leading transport systems for Aerobes and Anaerobes



collection & transportation

**M40**  
COMPLIANT

# Transwab®



# Medical Wire – Compliance with CLSI M40-A

Since the launch in 1975 of Transwab<sup>®</sup>, the world's first commercially produced all-in-one transport swab, Medical Wire has remained committed to the quality of its products, ensuring reliable handling of the patient's specimen, and dependable performance for all of our laboratory colleagues.

Accordingly, Medical Wire was one of the early adopters of CLSI's M40-A standard, implementing the requirements of the then proposed standard (M40-P) in 2001. We have always seen it as an essential reference to measure and where possible improve the performance of existing products, and for the development of new transport devices.

This document provides details of those of our products for which M40-A is relevant, with details of compliance.

## Reference

CLSI. 'Quality Control of Microbiological Transport Systems'; *Approved Standard M40-A*. CLSI (formerly NCCLS) document M40-A [ISBN 1-56238-520-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

## Purpose of M40-A

CLSI's<sup>a</sup> document M40-A was first published as an approved standard in 2003<sup>b</sup> by the then NCCLS<sup>c</sup>. It set out criteria for the guidance of manufacturers of microbiological transport devices, including urine specimen containers, blood culture bottles, and transport swabs. These same criteria were also intended to assist end users in assessing the relative performance characteristics of available devices.

The essential requirement of M40-A is to show that the microbiological quality of a patient's

specimen is being maintained in a stable manner during the anticipated transport period and conditions. In the case of transport swabs where live microorganisms are required to remain viable without drastic increase or decrease in numbers, the performance is assessed with a set of ten specified ATCC strains of bacteria in categories of aerobes, anaerobes, and fastidious organisms. Survival is assessed for up to 48 hours at either ambient or refrigeration temperatures. Swabs for virology are assessed using specified viruses. Transport swabs which are intended for a more restricted set of criteria can be assessed, but the limitations of any claims must be clearly stated.

Since publication, M40-A has become established as the international benchmark for transport devices, perhaps particularly in relation to transport swabs for bacteriology and virology. Many studies have been presented or published invoking its requirements, although sadly not all such "studies" are genuine, and may show conclusions which cannot be reconciled with the data presented.

## Notes

- a. CLSI : Clinical Laboratory Standards Institute
- b. M40-A is currently being revised, and will be reissued in the near future as CLSI M40-A2
- c. NCCLS: National Committee for Clinical Laboratory Standards

Please note CLSI M40-A is a copyrighted document and copies can be purchased from Clinical Laboratory Standards Institute at [www.clsi.org](http://www.clsi.org)



## State-of-the-art Transwab design:

Colour coded cap and label for ease of identification.

Unique Safety "Bell Cap": preventing the user's fingers coming into contact with swab or transport tube.

Dual action "Bell Cap" ensure containment of specimen during transit.

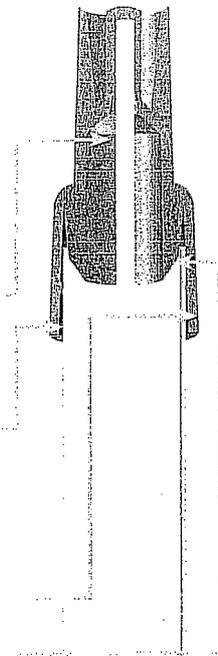
Shrouded Safety bell cap tightly grips the **inside** and **outside** of the tube.

Generous 5ml fill of semi solid medium provides optimum conditions for fastidious anaerobes.

Oxygen reduced medium enhanced for fastidious anaerobes.

Low Bio Burden - 1 non-viable bacterial cell per 20 high powered microscopic fields.

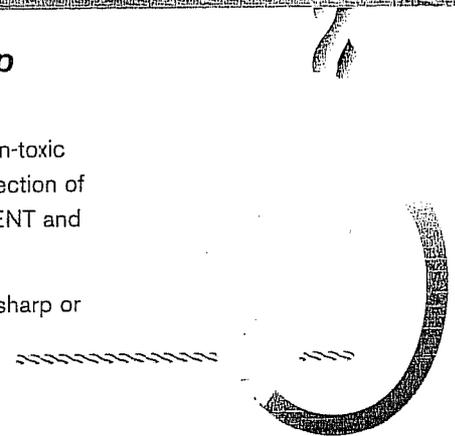
Rayon swab is non-toxic to microorganisms and provides both good absorption and retrieval of specimen.



## Unique safe loop design

Looped wire swab with non-toxic soft rayon for the safe collection of nasopharyngeal, urethral, ENT and pediatric specimens.

No risk to patients due to sharp or exposed edges.



## Quality Control

Transwab® is manufactured and tested in accordance with the requirements of CLSI (formerly NCCLS) M40-A Quality Control of Microbiological Transport Systems; approved Standard. Transwab complies with the requirements of M40-A for the transport of specimens including Aerobes and Facultative Anaerobes, Anaerobes and Fastidious Microorganisms at refrigeration temperatures (4°C - 8°C) or at ambient temperatures (20°C - 25°C).

Transwab® is CE-marked and validated as a Class IIa medical device in compliance with the European Medical Devices Directive 93/42 EEC.

Transwab® is CE-marked and validated in accordance with the European In Vitro Diagnostic Devices Directive 98/79/EC.

Transwab® is an ISO 9001:2000 certified device.

Transwab® is an ISO 13485:2003 certified device.

Transwab® is licensed as a Class II Medical Device by Health Canada (Medical Devices Bureau).

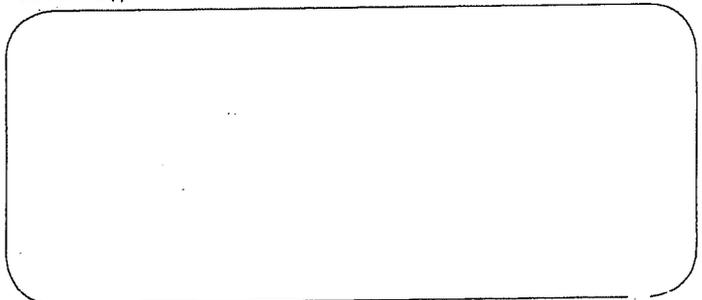
A large panel of NCTC and ATCC organisms are used in the final testing of each batch to ensure Transwab meets the demanding requirements of its customers.

**Transwab the choice for Aerobes and Facultative Anaerobes** including *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Haemophilus influenzae*.

**Transwab the choice for Anaerobes** including *Bacteroides fragilis*, *Peptostreptococcus anaerobius*, *Fusobacterium nucleatum*, *Propionibacterium acnes*, *Prevotella melaninogenica*.

**Transwab the choice for Fastidious Bacteria** including *Neisseria gonorrhoeae*.

Dealer stamp



**Aerobe & Anaerobe  
Guaranteed**  
You have our quality assurance

**Medical Wire & Equipment Co. (Bath) Ltd**  
Corsham, Wiltshire, England SN13 9RT  
Telephone: +44(0)1225 810361 Fax: +44(0)1225 810153

**MW&E**

## **TRANSWAB – transportinė sistema mėginiams paimti ir transportuoti (skirta aerobiniams ir anaerobiniams mikroorganizmams)**

TRANSWAB yra patentuotos transportinės sistemos skirtos saugiam aerobinių ir anaerobinių bakterijų mėginių paėmimui ir transportavimui.

TRANSWAB MW170 mėginių transportinė sistema su modifikuota Amies terpe (su arba be anglies).

### **PAGRINDINĖS TRANSWAB CHARAKTERISTIKOS:**

- patentuota ir saugi varpelio formos („Bell Cap“) kamštelio forma, užtikrinanti maksimalią apsaugą vartotojui ir paimtam mėginiui;
- transportinė sistema užtikrina maksimalų mikroorganizmų gyvybingumą gabenimo metu;
- paprasta ir saugu naudoti;
- kokybės ir patikimumo garantija;
- didelis deguonį mažinančios terpės tūris;
- atitinka M40 reikalavimus (užtikrinamas 24-48val. paimtų mikroorganizmų (aerobų ir anaerobų) gyvybingumas).

TRANSWAB mėginių transportinės sistemos yra padidinto patikimumo sistemos pritaikytos ir įnoringiems anaerobams. Gamintojo patvirtintas ir griežtai kontroliuojamas sterilizavimo procesas užkerta kelią transportinės terpės oksidacijai ir toksiškų superoksido formavimuisi. Kartu su dideliu tūriu deguonį mažinančios modifikuotos Amies terpės - tai užtikrina optimalias sąlygas anaerobiniams ir kitiems įnoringiems mikroorganizmams transportuoti.

TRANSWAB transportinė sistema su Amies terpe.

Amies terpė yra gaminama naudojant neorganinį fosfatinį buferį (Stiuarto terpei naudojamas glicerofosfatinis buferis gali sudaryti sąlygas koliformų ir gram-neigiamų rūšių peraugimui).

Kiekviena Transwab partija su Amies terpe yra testuojama naudojant aerobus, fakultatyvinius anaerobus, anaerobus ir įnoringus mikroorganizmus:

- *Neisseria gonorrhoeae*;
- *Bacteroides fragilis*;
- A grupės streptokokas;
- *Bordetella pertussis*;
- *Clostridium perfringens*;
- *Escherichia coli*;
- *Haemophilus influenzae*;
- *Staphylococcus aureus*;
- *Pseudomonas aeruginosa*.

### **KOKYBĖS KONTROLĖ**

TRANSWAB transportinė sistema yra CE ženklą turintis produktas atitinkantis Ila klasės medicinos gaminių pagal Europos medicinos priemonių direktyvą 93/42/EEC.

TRANSWAB atitinka DIN 58942-4:2000 reikalavimus. ISO 9001 sertifikuotas produktas.

Atitinka standarto CLSI M40-A reikalavimus.

VERTINAMAS ATITIKKA TURINYS

direktorius Algandras Poderas

A Poderas



2016-03-18