

DECLARATION OF CONFORMITY

Beckman Coulter Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):

B1010-40A (250mL) MicroScan Mineral Oil
B1010-40 (60mL) MicroScan Mineral Oil
B1010-41A (30mL) MicroScan Kovac's Reagent
B1010-41 (250mL) MicroScan Kovac's Reagent
B1010-42A (1.5g) Microscan Alpha Naphthol
B1010-43A (30mL) Microscan 40% Potassium Hydroxide
B1015-43 (250mL) Microscan 40% Potassium Hydroxide
B1010-44A (30mL) Microscan 0.8% Sulfanilic Acid
B1010-44 (250mL) Microscan 0.8% Sulfanilic Acid
B1010-45A (30mL) Microscan 0.5% N,N-Dimethylalphanaphthylamine
B1015-45 (250mL) Microscan 0.5% N,N-Dimethylalphanaphthylamine
B1010-48A (30mL) Microscan 10% Ferric Chloride
B1015-48 (250mL) Microscan 10% Ferric Chloride
B1012-30B (30mL) Microscan Peptidase
B1015-30 (250mL) Microscan Peptidase
B1015-3 (30mL) Microscan 0.05N Sodium Hydroxide
B1015-42 (250mL) Microscan 0.05N Sodium Hydroxide
B1015-15 (30mL) Microscan HNID Indole Reagent
B1015-5 (30mL) Microscan Xylene
B1015-6 (30mL) Microscan Ehrlich's Reagent

Device Group:

W020301

BUDI-DI:

15099501MCRGNTJJ

Risk Class:

Class A, Rule 5(a) (Article 47 in accordance with Annex VIII)

Intended Purpose:**Intended Use:**

MicroScan Mineral Oil is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Mineral Oil is an in vitro diagnostic accessory which aids as an oil overlay for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2, Gram Pos ID Panel Type 3, HNID, and Rapid Anaerobe ID panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan Kovac's Reagent is for use with MicroScan panels.

Intended User:**Authorized Representative (AR)**

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AR SRN: IE-AR-000000886

Conformity Assessment Procedure:

Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Kovac's Reagent is an in vitro diagnostic accessory which aids in the detection of metabolism of tryptophan for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2 panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan Alpha Naphthol is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Alpha Naphthol is an in vitro diagnostic accessory which aids in the detection of Acetoin in the Voges-Proskauer (VP) test for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2, Gram Pos ID Panel Type 3 instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan 40% Potassium Hydroxide is for use with MicroScan panels

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan 40% Potassium Hydroxide is an in vitro diagnostic accessory which aids in the detection of Acetoin in the Voges-Proskauer (VP) test for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2, Gram Pos ID Panel Type 3 instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan 0.8% Sulfanilic Acid is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan 0.8% Sulfanilic Acid is an in vitro diagnostic accessory which aids in the detection of nitrate reduction for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2, Gram Pos ID Panel Type 3, HNID, and Rapid Anaerobe ID panel instructions for methods of incubation and results.

Intended Use:

MicroScan 0.5% N,N-Dimethylalphanaphthylamine is for use with MicroScan panels

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan 0.5% N,N-Dimethylalphanaphthylamine is an in vitro diagnostic accessory which aids in the detection of nitrate reduction for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2, Gram Pos ID Panel Type 3, HNID, and Rapid Anaerobe ID panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan 10% Ferric Chloride is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan 10% Ferric Chloride is an in vitro diagnostic accessory which aids in the detection of indole pyruvic acid in Tryptophan Deaminase (TDA) tests for qualitative bacterial identification. Refer to MicroScan Gram Neg ID Panel Type 2 instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan Peptidase is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Peptidase is an in vitro diagnostic accessory which aids in the detection of β -Naphthylamine for qualitative bacterial identification. Refer to MicroScan Gram Pos ID Panel Type 3, HNID, Rapid Anaerobe ID, and Rapid Yeast ID panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan HNID Indole Reagent is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan HNID Indole Reagent is an in vitro diagnostic accessory which aids in the detection of indole for qualitative bacterial identification. Refer to MicroScan HNID panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan 0.05N Sodium Hydroxide is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan 0.05N Sodium Hydroxide is an in vitro diagnostic accessory which if the appropriate enzyme is present, the nitrophenyl substrate is cleaved releasing ortho- or para-nitrophenol. If the reaction occurs at an acidic pH, NaOH must be added after incubation before the results can be read. Refer to MicroScan Rapid Yeast ID panel instructions for methods of incubation and results determination which may include manual, semi-automated, or full automation on MicroScan instrumentation.

Intended Use:

MicroScan Xylene is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Xylene is an in vitro diagnostic accessory which aids in the detection of metabolism of tryptophan for qualitative bacterial identification. Xylene extracts the indole from the broth and concentrates it, the Ehrlich's Reagent reacts with the indole. Refer to MicroScan Rapid Anaerobe ID panel instructions for manual incubation and results determination.

Intended Use:

MicroScan Ehrlich's is for use with MicroScan panels.

Intended User:

This product is intended for laboratory professional use.

Clinical Relevance:

Not applicable, product is an IVD accessory.

Summary and Principles:

MicroScan Ehrlich's is an in vitro diagnostic accessory which aids in the detection of metabolism of tryptophan for qualitative bacterial identification. Xylene extracts the indole from the broth and concentrates it, the Ehrlich's Reagent reacts with the indole. Refer to MicroScan Rapid Anaerobe ID panel instructions for manual incubation and results determination.

Common Specification(s):

None

Signed for and on behalf of Beckman Coulter, Inc. the Legal Manufacturer.



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