

EU declaration of conformity

Division/Group: RAQA

Revision: 1en

see Product list in annex

REF see product list in annex

BUDI-DI: see product list in annex

GMDN code & term: see product list in annex



Bio-Rad
3 Boulevard Raymond Poincaré, Marnes-la-Coquette, 92430 France

SRN: FR-MF-000006261

EC REP : /

SRN : /

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s) / Directive(s):

- Regulation EU 2017/746 on *in vitro* Diagnostic medical devices

Risk CLASS:

- A B C D

CONFORMITY ROUTE

- ANNEX IX Technical Documentation Examination

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
 Expiration Date :

- ANNEX IX Quality Management System

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
 Expiration Date:

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EU declaration of conformity**Division/Group:** RAQA**Revision:** 1en ANNEX II+III**Common Specification (CS) :** /**Date of the first issuance of the EU Declaration of Conformity:** see product list in annex

Signature

Sylvie Fernez

Name

Marnes-la-Coquette

Issued in

June 7, 2022

Date

Assoc. Director Regulatory Affairs

Function

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Division/Group: RAQA
Revision: 1en
Product list annex

REF	Product name	BUDI-DI	GMDN code & term	Date of the first issuance of the EU Declaration of Conformity
53154	Coletsos agar	361052A001627W	58580 Coletsos Mycobacterium tuberculosis agar culture medium IVD	18 May 2022
53384	Hypertonic Broth	361052A003027N	58597 Enterococcus species salt-tolerance broth differential medium IVD	18 May 2022
53430	Sven Gard agar	361052A001637Y	58685 Basic/simple nutrient agar culture medium IVD	18 May 2022
53454	T.C.S. broth	361052A0006783	58687 Enriched broth culture medium IVD	18 May 2022
53664	Brain-Heart Infusion broth	361052A002598E	58553 Brain heart infusion (BHI) broth culture medium IVD	18 May 2022
55244	Löwenstein-Jensen agar	361052A0016584	58622 Lowenstein-Jensen Mycobacterium species agar culture medium IVD	18 May 2022
55313	Kovacs	361052A003057U	43720 Indole/Kovac's microbial reagent IVD	18 May 2022
55378	Kligler-Hajna agar	361052A002337U	58585 Differential/selective agar culture medium IVD	18 May 2022
55683	Rosenow Cysteine broth	361052A0025688	58536 Anaerobic broth culture medium IVD	18 May 2022
55746	Selenite Cysteine Broth	361052A0017383	58684 Differential/selective broth culture medium IVD	18 May 2022
56352	Rabbit Plasma	361052A003828E	42737 Coagulase production microbial reagent IVD	7 June 2022
56594	Sabouraud Chloramphenicol Gentamicin agar	361052A0007582	58604 Fungal antimicrobial susceptibility culture medium IVD	18 May 2022
56596	Sabouraud Chloramphenicol Gentamicin Actidione agar	361052A000727U	58604 Fungal antimicrobial susceptibility culture medium IVD	18 May 2022
63512	Butzler agar	361052A0016482	58585 Differential/selective agar culture medium IVD	18 May 2022
63524	Mueller-Hinton-F agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63525	Mueller-Hinton-F agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63617	MacConkey agar + Crystal Violet	361052A002578A	58585 Differential/selective agar culture medium IVD	18 May 2022
63619	MacConkey agar + Crystal Violet	361052A002578A	58585 Differential/selective agar culture medium IVD	18 May 2022

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REF	Product name	BUDI-DI	GMDN code & term	Date of the first issuance of the EU Declaration of Conformity
63683	Stock Culture agar	361052A0025586	58685 Basic/simple nutrient agar culture medium IVD	18 May 2022
63774	Sabouraud Chloramphenicol Gentamicin agar	361052A000747Y	58604 Fungal antimicrobial susceptibility culture medium IVD	18 May 2022
63784	Columbia agar+ 5% Sheep Blood	361052A0006987	58582 Columbia agar culture medium IVD, 5% sheep blood	18 May 2022
12016409	Columbia agar+ 5% Sheep Blood	361052A0006987	58582 Columbia agar culture medium IVD, 5% sheep blood	18 May 2022
63814	Salmonella-Shigella agar	361052A0016686	58585 Differential/selective agar culture medium IVD	18 May 2022
63824	Mueller-Hinton agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63825	Mueller-Hinton agar + Sheep Blood	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63829	Mueller-Hinton agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63884	T.C.S. agar	361052A000717S	58685 Basic/simple nutrient agar culture medium IVD	18 May 2022
63901	Mueller-Hinton agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63902	Mueller-Hinton + Sheep Blood agar	361052A0017485	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
63934	Chocolate agar PVS	361052A0016788	58688 Enriched agar culture medium IVD	18 May 2022
63945	Chocolate agar PVS VCAT	361052A001688A	58585 Differential/selective agar culture medium IVD	18 May 2022
63947	Chocolate agar PVS Bacitracin	361052A001698C	58585 Differential/selective agar culture medium IVD	18 May 2022
63953	Columbia CNA agar + 5% Sheep Blood	361052A0007684	58585 Differential/selective agar culture medium IVD	18 May 2022
63954	Columbia CNA agar + 5% Sheep Blood	361052A0007684	58585 Differential/selective agar culture medium IVD	18 May 2022
63994	B.E.A. agar	361052A001707V	58585 Differential/selective agar culture medium IVD	18 May 2022
64184	B.E.A. agar	361052A001717X	58585 Differential/selective agar culture medium IVD	18 May 2022
64514	Salmonella-Shigella agar	361052A001727Z	58585 Differential/selective agar culture medium IVD	18 May 2022
64554	T.C.S. agar	361052A000707Q	58685 Basic/simple nutrient agar culture medium IVD	18 May 2022

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REF	Product name	BUDI-DI	GMDN code & term	Date of the first issuance of the EU Declaration of Conformity
64558	T.C.S. agar	361052A000707Q	58685 Basic/simple nutrient agar culture medium IVD	18 May 2022
64644	Sabouraud Chloramphenicol agar	361052A000737W	58604 Fungal antimicrobial susceptibility culture medium IVD	18 May 2022
64674	Columbia agar	361052A0006885	58583 Columbia agar culture medium IVD, no blood	18 May 2022
64678	Columbia agar	361052A0006885	58583 Columbia agar culture medium IVD, no blood	18 May 2022
64884	Mueller-Hinton agar	361052A0017587	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
64888	Mueller-Hinton agar	361052A0017587	58605 General-microorganism antimicrobial susceptibility culture medium IVD	18 May 2022
69084	MacConkey agar	361052A002588C	58585 Differential/selective agar culture medium IVD	18 May 2022

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