

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



**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.: 38917**

Name of Notified Body : GMED

Notified Body Identification No.: 0459

Expiration Date: April 3, 2027

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 ANNEX II+III

Common Specification (CS) : /

Date of the first issuance of the EU Declaration of Conformity: see product list in annex

DocuSigned by:

0A5A30594ACE47B...

Marnes-la-Coquette

July 23, 2024

Signature

Issued in

Date

Christelle HERMAND

Regulatory Affairs Supervisor

Name

Function

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**Division/Group: RAQA**
**Revision: 1en**
**Annex - Product list**

<b>REF</b>	<b>Product name</b>	<b>BUDI-DI</b>	<b>GMDN code &amp; term:</b>	<b>Date of the first issuance of the EU Declaration of Conformity</b>
68250	β LACTA TEST	361052A000327G	43557 Beta-lactamase production microbial reagent IVD	April 27, 2022
68260	β CARBA test	361052A000337J	61275 Multiple bacteria carbapenemase production IVD, kit, chromogenic	April 27, 2022
63726	UriSelect4	361052A000257K	58585 Differential/selective agar culture medium IVD	April 27, 2022
63727	UriSelect4	361052A000257K	58585 Differential/selective agar culture medium IVD	April 27, 2022
64694	UriSelect4	361052A000317E	58585 Differential/selective agar culture medium IVD	April 27, 2022
12013236	UriSelect4	361052A000317E	58585 Differential/selective agar culture medium IVD	April 27, 2022
63740	CandiSelect	361052A000267M	58585 Differential/selective agar culture medium IVD	April 27, 2022
63748	SaSelect	361052A000277P	58585 Differential/selective agar culture medium IVD	April 27, 2022

**Susceptibility Disks**

<b>REF</b>	<b>Product name</b>	<b>BUDI-DI</b>	<b>GMDN code &amp; term:</b>	<b>Date of the first issuance of the EU Declaration of Conformity</b>
66068	TEMOCILLIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66098	CEFEPIME 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66128	AMPICILLIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	July 23, 2024
66148	AMIKACIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66178	AMOXICILLIN + CLAVULANIC ACID 20 / 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66188	CEFTRIAZONE 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66198	CARBENICILLIN 100 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66208	CEFALEXIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022

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66218	CEPHALOTHIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66228	CEFOXITIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66258	CEFAZOLIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66278	CHLORAMPHENICOL 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66308	CEFTAZIDIME 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66328	CLINDAMYCIN 2 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66338	NORFLOXACIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66358	CEFUROXIME 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66368	CEFOTAXIME 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66388	DOXYCYCLINE 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66448	ERYTHROMYCIN 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66518	FUSIDIC ACID 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66568	IMIPENEM 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66608	GENTAMICIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66618	KANAMYCIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66648	RIFAMPICIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66680	AMOXICILLIN + CLAVULANIC ACID 2/1 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66728	MINOCYCLINE 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022

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66758	NETILMICIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66768	MECILLINAM 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66858	LEVOFLOXACIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66888	OXACILLIN 1µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66918	CEFPODOXIME 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
66928	AZTREONAM 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67008	AZITHROMYCIN 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67018	AMPICILLIN +SULBACTAM 10 / 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67048	MEROPENEM 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67058	CLARITHROMYCIN 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67078	MUPIROCIN 200 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67098	MOXIFLOXACIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67218	PENICILLIN 6 µg (10 IU)	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67228	PIPERACILLIN 100 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67238	PIPERACILLIN + TAZOBACTAM 100/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67268	COLISTIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67278	PRISTINAMYCIN 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67288	AMPICILLIN 2 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022

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67298	CEFTAZIDIME 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67318	GENTAMICIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67328	NITROFURANTOIN 100 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67338	PIPERACILLIN + TAZOBACTAM 30/6 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67388	LINEZOLID 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67398	TIGECYCLINE 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67418	STREPTOMYCIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67448	TETRACYCLINE 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67458	TICARCILLIN 75 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67468	TICARCILLIN 75 µg + CLAVULANIC ACID 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67488	TOBRAMYCIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67498	CEFACLOR 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67518	ERTAPENEM 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67528	QUINUPRISTIN-DALFOPRISTIN 15 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	June 20, 2022
67578	SULPHONAMIDES 300 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67588	CEFIXIME 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67598	GENTAMICIN (HIGH LOAD) 120 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67608	STREPTOMYCIN (HIGH LOAD) 300 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022

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67618	CEFOPERAZONE 75 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67638	CEFTIBUTEN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67658	FOSFOMYCIN 200 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67718	CEFOTAXIME 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67788	BENZYL PENICILLIN 1 IU	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67798	NETILMICIN 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67828	VANCOMYCIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
67878	LINEZOLID 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68039	CEFTOBIPROLE 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68040	CEFTOLOZANE + TAZOBACTAM 30/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68042	AMOXICILLIN 20 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68228	PEFLOXACIN 5µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68478	PIPERACILLIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68618	NALIDIXIC ACID 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68648	CIPROFLOXACIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68658	CEFTAROLINE 5µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68678	NITROFURANTOIN 300 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68798	SPECTINOMYCIN 100 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	June 20, 2022

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REF	Product name	BUDI-DI	GMDN code & term:	Date of the first issuance of the EU Declaration of Conformity
68888	TRIMETHOPRIM 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68898	TRIMETHOPRIM + SULFAMETHOXAZOLE 1,25/23,75 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68928	VANCOMYCIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
68938	OFLOXACIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	June 20, 2022
68948	TEICoplanin 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12007959	NITROXOLIN 30 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12008071	CEFTAZIDIME+ AVIBACTAM 10/4 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12010679	CEFOTAXIME + CLAVULANIC ACID 5/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12010680	CEFTAZIDIME + CLAVULANIC ACID 10/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12012123	CEFEPIME + CLAVULANIC ACID 30/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12012124	CEFTAZIDIME + AVIBACTAM 30/20 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12012125	CEFOTAXIME + CLAVULANIC ACID 30/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12012199	CEFTAZIDIME + CLAVULANIC ACID 30/10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	April 27, 2022
12016866	METRONIDAZOLE 5µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	June 20, 2022
12017942	LEFAMULIN 5 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	July 23, 2024
12017951	MEROPENEM + VABORBACTAM 20 / 10 µg	361052A000497Z	63834 Antibacterial susceptibility testing disc IVD	July 23, 2024

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