

**DICHIARAZIONE DI CONFORMITÀ CE**  
**EC DECLARATION OF CONFORMITY**

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.  
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**  
manufacturer **disposable labware**

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identificazione dei prodotti  
product identification

**Sistema di prelievo di sangue e altri liquidi biologici  
mediante provette con vuoto predeterminato in plastica  
"VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids  
collection tubes in plastic.**

nome commerciale  
brand name

**"VACUTEST KIMA"**

classificazione dei prodotti  
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.  
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

**Si dichiara**

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

**Hereby we declare**

*under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".*

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data  
place and date

**Arzergrande, 01/01/2015**

firma  
signature

**Assicuratore Qualità / Quality Manager  
Giovanni Chiarin**



## DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

### DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 31.0 del 08.01.2016

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

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### EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the *in vitro* medical-diagnostic device listed in the attached table, Revision 31.0 of 08.01.2016

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 08.01.2016

Direttore Tecnico/ Technical Director  
Dott. Silvio Brocco



# PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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10002	DNA AGAR + BLU DI TOLUIDINA
10004	CLED ANDRADE AGAR
10004*	CLED ANDRADE AGAR
10005	MAC CONKEY SORBITOL AGAR
10005*	MAC CONKEY SORBITOL AGAR
10006	TRYPTIC SOY AGAR + 0,6% YEAST EXTRACT
10007	BACILLUS CEREUS AGAR (PEMBA)
10007*	BACILLUS CEREUS AGAR (PEMBA)
10011	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10011*	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10013	DNase TEST AGAR
10013*	DNase TEST AGAR
10014	Purple Lactose Agar
10014*	Purple Lactose Agar
10017	CZAPEK DOX AGAR
10018	DRIGALSKY LACTOSE AGAR
10021	BIGGY (NICKERSON) AGAR
10021*	BIGGY (NICKERSON) AGAR
10022	BRILLIANT GREEN AGAR
10022*	BRILLIANT GREEN AGAR
10023	Chocolate Agar
10023*	Chocolate Agar
10024	TRYPTOSE AGAR
10024*	TRYPTOSE AGAR
10025	COLUMBIA AGAR (Horse Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)
10026	CLED AGAR
10026*	CLED AGAR
10027	BACILLUS CEREUS AGAR (Mossel)
10027*	BACILLUS CEREUS AGAR (Mossel)
10028	ISOSENSITEST AGAR
10028*	ISOSENSITEST AGAR
10029	MAC CONKEY AGAR
10029*	MAC CONKEY AGAR
10030	MANNITOL SALT AGAR
10030*	MANNITOL SALT AGAR
10031	MUELLER HINTON II AGAR
10031*	MUELLER HINTON II AGAR
10033	PSEUDOMONAS (CETRIMIDE ) AGAR
10033*	PSEUDOMONAS (CETRIMIDE ) AGAR
10035	SABOURAUD AGAR
10035*	SABOURAUD AGAR
10035S	SABOURAUD AGAR Irradiated
10036	S.S. AGAR
10036*	S.S. AGAR
10037	TRYPTIC SOY AGAR
10037*	TRYPTIC SOY AGAR
10037S	TRYPTIC SOY AGAR Irradiated
10039	ROGOSA AGAR
10039*	ROGOSA AGAR
10040	NEW YORK CITY AGAR
10040*	NEW YORK CITY AGAR
10041	LISTERIA PALCAM AGAR
10041*	LISTERIA PALCAM AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)
10042*	CRYSTAL VIOLET AGAR (Sheep 5%)
10043	HEKTOEN ENTERIC AGAR
10043*	HEKTOEN ENTERIC AGAR
10044	NUTRIENT AGAR
10044*	NUTRIENT AGAR

10046	SERUM TELLURITE AGAR
10047	BISMUTH SULFITE AGAR
10047*	BISMUTH SULFITE AGAR
10048	E.M.B. LEVINE AGAR
10048*	E.M.B. LEVINE AGAR
10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10051	Legionella BCYE Agar
10051*	Legionella BCYE Agar
10052	YERSINIA SELECTIVE AGAR
10052*	YERSINIA SELECTIVE AGAR
10053	WILKINS CHALGREEN AGAR
10053*	WILKINS CHALGREEN AGAR
10054	WURTZ LACTOSE AGAR
10054*	WURTZ LACTOSE AGAR
10056	X.L.D. AGAR
10056*	X.L.D. AGAR
10057	BILE AESCULIN AGAR
10057*	BILE AESCULIN AGAR
10058S	TRYPTIC SOY AGAR Irradiated -30 mL-
10060	BRAIN HEART INFUSION AGAR
10060*	BRAIN HEART INFUSION AGAR
10064	CHRISTENSEN UREA AGAR
10065	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10065*	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10067	SCHAEDLER KVN AGAR (Sheep Blood 5%)
10069	X.L.T. 4 AGAR
10069*	X.L.T. 4 AGAR
10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10078	MUELLER HINTON II MOD. AGAR
10078*	MUELLER HINTON II MOD. AGAR
10079	CASITONE AGAR
10079*	CASITONE AGAR
10080	HAEMOPHYLUS TEST AGAR
10080*	HAEMOPHYLUS TEST AGAR
10082	HELICOBACTER PYLORI AGAR
10082*	HELICOBACTER PYLORI AGAR
10090	M.R.S. Agar
10090*	M.R.S. Agar
10095	BRAIN HEART AGAR FOR HAEMOPHILUS
10129	MAC CONKEY AGAR MMG
10129*	MAC CONKEY AGAR MMG
10131	Mueller Hinton II Agar (Sheep Blood 5%)
10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10132	MUELLER HINTON FASTIDIOUS AGAR 90 mm
10134	Legionella BMPA Agar
10141	SALMONELLA TEST AGAR
10141*	SALMONELLA TEST AGAR
10142	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10142*	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10143	Mueller Hinton Agar + 5 % Horse Blood Lysed
10145	CAMPYLOBACTER KARMALI AGAR
10146	CAMPYLOBACTER PRESTON AGAR
10148	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10225	LISTERIA PALCAM AGAR 140 mm
10231	MUELLER HINTON II AGAR 140 mm
10233	R.P.M.I. AGAR
10235	SABOURAUD CAF AGAR + GENTAMICIN
10235*	SABOURAUD CAF AGAR + GENTAMICIN
10236	CLED AGAR 140 mm

# PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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10240	SCHAEDLER K AGAR (Sheep Blood 5%) 140mm
10241	SCHAEDLER KKV AGAR(Sheep blood 5%) 140mm
10242	SABOURAUD CAF AGAR 140 mm
10243	SABOURAUD CAF AGAR + GENTAMICIN 140mm
10244	DERMATOPHYTE (D.T.M.) AGAR 140 mm
10245	BRUCELLA BLOOD AGAR w HEMIN AND VITAMIN K1
10246	Chromatic™ MH
10247	Brucella Blood Agar with Hemin and Vitamin K1
10249	Purple Lactose Agar 140 mm
10334	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10334*	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10335	MUELLER HINTON CHOCOLATE AGAR
10353	BORDET GENGOU AGAR (Sheep Blood 15%)
10353*	BORDET GENGOU AGAR (Sheep Blood 15%)
10405	SCHAEDLER CNA AGAR (Sheep Blood 5%)
10407	VANCOMYCIN SCREEN AGAR
10408	WILKINS CHALGREN AGAR +5% SHEEP BLOOD
10409	CAMPYLOBACTER CCDA AGAR
10410	MUELLER HINTON AGAR w VITALEX
10411	BILE ESCULIN AZIDE AGAR w VANCOMYCIN
10412	Legionella BCYE Agar w/o Cysteine
10413	XLD Agar EP, USP, JP Formulation
10416	MIDDLEBROOK 7H11 AGAR
10424	Legionella BCYE Agar w Vancomycin + Colistin
10425	SCEDOSPORIUM SELECTIVE AGAR
10438	MacConkey Agar No.2
10438*	MacConkey Agar No.2
10439	Group A Selective Strep Agar w/ 5% Sheep Blood
10599	CHROMATIC™ MRSA
10600	OXACILLIN RESISTANCE STAPHYLOCOCCUS AGAR
10601	CHOCOLATE AGAR w/o VITOX
10602	CAMPYLOBACTER SKIRROW AGAR
10605	HELICOBACTER PYLORI EGG YOLK EMULSION AGAR
10620	O.A.LISTERIA
11023	CHOCOLATE BACITRACIN AGAR
11023*	CHOCOLATE BACITRACIN AGAR
11024	COLUMBIA CNA AGAR (Sheep Blood 5%)
11024*	COLUMBIA CNA AGAR (Sheep Blood 5%)
11025	COLUMBIA AGAR (Sheep Blood 5%)
11025*	COLUMBIA AGAR (Sheep Blood 5%)
11027	DESOXYCHOLATE AGAR
11027*	DESOXYCHOLATE AGAR
11030	ANAEROBIC AGAR
11033	PSEUDOMONAS ISOLATION AGAR
11033*	PSEUDOMONAS ISOLATION AGAR
11035	SABOURAUD CAF AGAR
11035*	SABOURAUD CAF AGAR
11035S	SABOURAUD CAF AGAR Irradiated
11037	TRYPTIC SOY AGAR (Sheep Blood 5%)
11037*	TRYPTIC SOY AGAR (Sheep Blood 5%)
11038	TRYPTIC SOY AGAR (Horse Blood 5%)
11038*	TRYPTIC SOY AGAR (Horse Blood 5%)
11040	THAYER MARTIN AGAR
11040*	THAYER MARTIN AGAR
11041	AZIDE AGAR (Sheep Blood 5%)
11041*	AZIDE AGAR (Sheep Blood 5%)
11052	DERMATOPHYTE (D.T.M.) AGAR
11052*	DERMATOPHYTE (D.T.M.) AGAR
11054	GARDNERELLA AGAR (Sheep Blood 5%)
11054*	GARDNERELLA AGAR (Sheep Blood 5%)

11057	ENTEROCOCCO AGAR
11057*	ENTEROCOCCO AGAR
11058	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11058*	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11060	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11060*	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11065	SCHAEDLER K AGAR (Sheep Blood 5%)
11065*	SCHAEDLER K AGAR (Sheep Blood 5%)
11070	MYCOSEL AGAR
11070*	MYCOSEL AGAR
11132	MUELLER HINTON FASTIDIOUS AGAR (140mm)
11124	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11124*	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11135	SABOURAUD AGAR MODIFIED
11135*	SABOURAUD AGAR MODIFIED
11143	HERELLEA AGAR
11143*	HERELLEA AGAR
11185	VOGEL JOHNSON AGAR
11185*	VOGEL JOHNSON AGAR
11195	T.C.B.S. AGAR
11195*	T.C.B.S. AGAR
11196	SPS AGAR
11196*	SPS AGAR
11200	PAR TEST AGAR
11200*	PAR TEST AGAR
11205	MYCOPLASMA AGAR
11206	Mueller Hinton II Agar + 2% NaCl
11231	Mueller Hinton II Agar (Sheep Blood 5%) 140mm
11235	SABOURAUD CAF AGAR + TTC
11235*	SABOURAUD CAF AGAR + TTC
11236	Sabouraud CAF Agar + Actidione
11250	TINSDALE AGAR
11250*	TINSDALE AGAR
11335	SABOURAUD AGAR + GENTAMICIN
11335*	SABOURAUD AGAR + GENTAMICIN
11501	ENTEROCOCCUS AGAR + VANCOMYCIN
11506	BURKHOLDERIA CEPACIA SELECTIVE AGAR
11509	R.P.M.I. AGAR
11510	M.HINTON+GLUCOSE+METHYLEN BLUE
11511	NEISSERIA-MORAXELLA MEDIUM
11512	NUTRIENT AGAR acc.to ISO 21528
11513	NUTRIENT AGAR acc.to ISO 6579
11517	COLUMBIA AGAR(Sheep Blood 5%)+VANCOMYCIN
11518	Mueller Hinton Agar + Cloxacillin
11610	Chromatic™ E.coli O157
11611	CHROMATIC™ DETECTION
11612	CHROMATIC™ CANDIDA
11614	CHROMATIC™ SALMONELLA
11616	CHROMATIC™ STAPH AUREUS
11617	CHROMATIC™ STREPTO B
11618	CHROMATIC™ MH
11619	CHROMATIC™ CRE
11621	CHROMATIC™ VRE
11622	CHROMATIC™ ESBL
11627	Chromatic™ Enterococcus
11629	CHROMATIC™ ESBL + AmpC
11629*	CHROMATIC™ ESBL + AmpC
11631	Chromatic™ OXA-48
11632	Chromatic™ Clostridium difficile
11634	Chromatic™ Detection opaque



# PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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12031	MUELLER HINTON II AGAR (120X120 mm)
12032	Mueller Hinton II Agar (Sheep Blood 5%) (120 mm x 120 mm)
12033	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (120 mm x 120 mm)
13012	CLED/MACCONKEY/TSA BLOOD AGAR
13012*	CLED/MACCONKEY/TSA BLOOD AGAR
13013	BAIRD PARKER/BIGGY/MACCONKEY
13013*	BAIRD PARKER/BIGGY/MACCONKEY
13014	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13014*	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13017	CLED/MACCONKEY MMG/MALTO
13017*	CLED/MACCONKEY MMG/MALTO
13018	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13018*	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13019	CLED/MACCONKEY/CETRIMIDE
13019*	CLED/MACCONKEY/CETRIMIDE
13020	MAC CONKEY/B.PARKER/TSA BLOOD
13345	GARDNERELLA V./ROGOSA/THAYER MARTIN
13345*	GARDNERELLA V./ROGOSA/THAYER MARTIN
13356	Gard.V. / Chocolate / Thayer Martin
13371	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13371*	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13480	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13480*	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13602	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13602*	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13607	CHOC. BAC./COLUMBIA/MAC CONKEY
13607*	CHOC. BAC./COLUMBIA/MAC CONKEY
13614	CLED/MACCONKEY/ENTEROCOCCO
13614*	CLED/MACCONKEY/ENTEROCOCCO
165312	MYCOPLASMA AGAR
18007	CHROMATIC™ STAPH AUREUS/ MRSA
18008	TSA BLOOD/CROMagar ORIENTATION
18008*	TSA BLOOD/CROMagar ORIENTATION
18009	Chromatic™ Salmonella/Hektoen Enteric
18011	CHROMATIC™ DETECTION/ESBL
18012	BRILLIANT GREEN / SS AGAR
18012*	BRILLIANT GREEN / SS AGAR
18015	BIGGY (NICKERSON) / MALT AGAR
18015*	BIGGY (NICKERSON) / MALT AGAR
18017	COLUMBIA CNA BLOOD/CHROMAGAR
18017*	COLUMBIA CNA BLOOD/CHROMAGAR
18018	MAC CONKEY/ SABOURAUD CAF
18020	EMB LEVINE / TSA BLOOD
18020*	EMB LEVINE / TSA BLOOD
18021	Chromatic™ CRE / Chromatic™ ESBL
18021*	Chromatic™ CRE / Chromatic™ ESBL
18022	TSA Blood/Columbia CNA
18327	COLUMBIA CNA / MAC CONKEY
18327*	COLUMBIA CNA / MAC CONKEY
18379	GARDNERELLA V. / THAYER MARTIN
18379*	GARDNERELLA V. / THAYER MARTIN
18380	MAC CONKEY / TSA BLOOD
18380*	MAC CONKEY / TSA BLOOD
18390	BAIRD PARKER / SABOURAUD CAF
18390*	BAIRD PARKER / SABOURAUD CAF
18391	HEKTOEN ENTERIC / YERSINIA
18391*	HEKTOEN ENTERIC / YERSINIA
18422	COLUMBIA CNA / GARDNERELLA
18422*	COLUMBIA CNA / GARDNERELLA

18500	BAIRD PARKER / MAC CONKEY
18500*	BAIRD PARKER / MAC CONKEY
18502	CLED / MAC CONKEY
18502*	CLED / MAC CONKEY
18503	HEKTOEN ENTERIC / SS
18503*	HEKTOEN ENTERIC / SS
18505	MAC CONKEY / S.S.AGAR
18505*	MAC CONKEY / S.S.AGAR
18507	COLUMBIA CNA / CHOCOLATE
18507*	COLUMBIA CNA / CHOCOLATE
18595	D.T.M. / SABOURAUD
18595*	D.T.M. / SABOURAUD
18700	Group A Selective/TSA II + Sheep Blood 5%
18703	CHOCOLATE AGAR /THAYER MARTIN
20075	MAC CONKEY BROTH(7516MC2) 20x5ml
20077	PHYSIOLOGICAL SOLUTION 2.5 ml
20079	PHYSIOLOGICAL SOLUTION 4.5 ML
20081	INOCULUM SOLUTION 5 ML
20089	SUSPENSION BROTH
20090	HELICOBACTER PYLORI TEST
20095	PHYSIOLOGICAL SOLUTION
20098	PEPTONE WATER
20105	Glucose Broth
20121	INOCULUM BROTH 7 ML
20129	TRYPTIC SOY BROTH 15 ml
20136	TRYPTONE WATER
20140	PURPLE LACTOSE BROTH
20156	SUSPENSION MEDIUM 7 ML
20158	MYCOPLASMA TRANSPORT BROTH
20159	TRICHOMONAS BROTH w/o CLORAMPHENICOL
20171	Thioglycollate Medium w Vit.K1 & Hemin
20340	VAGITUBE
21104	TRYPTIC SOY BROTH
21110	SELENITE BROTH
21241	Fluid Thioglycollate Medium
22130	SCHAEDLER BROTH
23001	F.B. FASTIDIOUS BROTH
23002	MUELLER HINTON BROTH w HORSE BLOOD (11ml)
23003	MUELLER HINTON BROTH
24070	MYCOSEL BROTH 20PV
24071	Cooked Meat Medium
24091	HAEMOPHILUS TEST BROTH 20 PV
24098	PEPTONE WATER 20PV
24100	ALKALINE PEPTONE WATER 20PV
24103	NUTRIENT BROTH 20PV
24104	BRAIN HEART INFUSION BROTH 20PV
20105	Glucose Broth
24107	MUELLER HINTON II BROTH 20 PV
24108	MULLER KAUFFMANN BROTH 20PV
24109	SABOURAUD BROTH (Harm.EP) 20PV
24110	SELENITE BROTH 20PV
24111	TODD HEWITT BROTH 20PV
24112	TRYPTOSE BROTH 20PV
24115	TRICHOMONAS BROTH 20PV
24117	Pergola Broth
24119	GN HAJNA BROTH 20PV
24120	BILE AESCULIN BROTH 20PV
24124	Fluid Thioglycollate Medium
24125	SERUM BROTH 20PV
24127	Fluid Thioglycollate Medium + 1% Tween 80

# PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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24128	TRYPTIC SOY BROTH + TWEEN 80 1% 20PV
24135	SALMONELLA DIFFERENTIAL BROTH 20PV
24136	TRYPTONE WATER 20PV
24137	MALONATE BROTH 20PV
24139	LYSINE DECARBOXYLASE BROTH 20PV
24141	BRAIN HEART INFUSION BROTH 2 ml 20PV
24142	PHYSIOLOGICAL SOLUTION 3ml 20PV
24144	TODD HEWITT w Gentam/Nalidixic acid 20PV
24145	TODD HEWITT B. w Colistin/Nalid.a. 20PV
24146	THIOGLYCOLLATE M w/o INDICATOR acc.USP 20PV
24147	Thioglycollate Bile
24149	MR-VP MEDIUM 20PV
24161	Sabouraud Dextrose Broth + CAF
24241	Fluid Thioglycollate Medium
24342	MOTILITY TEST MEDIUM 20PV
24345	O.F. Medium with Glucose
24400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH 20PV
24403	BIOTONE BROTH 20PV
24404	CAMPYLOBACTER BROTH 20PV
24411	S.F. BROTH 20PV
24412	STREPTOCOCCUS BROTH 20PV
24413	MOSEL AND MARTIN w MANNITOL 20PV
24416	UREA BROTH 20PV
24417	Wilkins Chalgren Broth
24430	SCHAEDLER BROTH 20PV
24432	YERSINIA BROTH 20PV
24433	EUGON BROTH 20PV
24436	MIDDLEBROOK 7H9 BROTH 20PV
24446	PHENOL RED BROTH 20PV
24450	Rappaport Broth w/o Soy
24451	Tetrathionate Broth
24459	CASO BROTH (Double Concentration) CE 20PV
24461	RPMI Broth
24462	RPMI Broth (double strength)
24513	TRYPTIC SOY BROTH (Harm.EP)
24514	TRYPTIC SOY BROTH
24516	UREA BROTH
26105	Glucose Broth
26124	Fluid Thioglycollate Medium 100 x 10 ml
26400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH
26513	Tryptic Soy Broth
27001	GESA MEDIUM
27500	Triptic Soy Broth
27501	Todd Hewitt Broth
27502	Brain Heart Infusion Broth
27503	Nutrient Broth
29000	CHECK-SET BROTH Irradiated 20 Tests
30007	CAMPYLOBACTER SELECTIVE THIOGLYCOLLATE MEDIUM
30008	CLOSTRIDIUM AGAR (Sheep Blood 5%)
30009	HELICOBACTER PYLORI AGAR
30010	STREPTOCOCCAL KF + TTC AGAR
30011	SIMMONS CITRATE AGAR
30013	NITRATI AGAR
30014	MOSEL AGAR
30022	T.C.B.S. AGAR
30023	SABOURAUD CAF AGAR
30024	SABOURAUD CAF + ACTIDIONE AGAR
30030	M.R.S. AGAR
30080	BORDET GENGOU AGAR (Sheep Blood 15%)
30081	CHRISTENSEN UREA AGAR

30082	TRYPTIC SOY AGAR
30083	NUTRIENT AGAR
30084	BRAIN HEART INFUSION AGAR
30085	PHENYLALANINE AGAR
30087	KLIGLER IRON AGAR
30088	KLIGLER IRON AGAR + NaCl 2%
30090	Mueller Hinton II Agar
30091	BIGGY (NICKERSON) AGAR
30093	SABOURAUD AGAR
30095	SIM MEDIUM
30096	T.S.I. AGAR
30097	Tryptose Agar
30098	LYSINE IRON AGAR
30099	Chocolate Agar
30116	LOEFFLER MEDIUM
30117	PERGOLA MEDIUM
30118	Lowenstein Jensen Medium
30119	LOWENSTEIN JENSEN MEDIUM w/o GLYCEROL
30121	Stonebrink Medium
30125	DORSET EGG MEDIUM
30368	MIDDLEBROOK 7H10 AGAR
31065	SPS Agar
31075	Mueller Hinton II Agar
31090	Mueller Hinton II Agar
31097	Tryptose Agar
31099	Chocolate Agar
31121	Stonebrink Medium
33040	THAYER MARTIN AGAR
33055	MYCOSEL AGAR
33060	SERUM TELLURITE AGAR
33066	O.N.P.G. AGAR
33085	BILE AESCULIN AGAR
33086	DERMATHOPHYTE (D.T.M.) AGAR
33118	I.U.T.M. MEDIUM
33120	PETRAGNANI MEDIUM
34070	CAMPYLOBACTER AGAR
34071	CYSTINE TRYPTIC AGAR (CTA)
34075	Mueller Hinton II Agar
34121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/mL
34121/1	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/mL
34121/2	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/mL
34121/3	LOWENSTEIN JENSEN + RIFAMPICIN 25 µg/mL
34121/4	LOWENSTEIN JENSEN + RIFAMPICIN 50 µg/mL
34121/5	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
34121/6	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
34122	LOWENSTEIN JENSEN + RIFAPENTIN 9 µg/mL
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/mL
34123/1	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/mL I
34123/2	LOWENSTEIN JENSEN + ISONIAZID 1 µg/mL
34123/3	LOWENSTEIN JENSEN + ISONIAZID 5 µg/mL
34123/4	LOWENSTEIN JENSEN + ISONIAZID 10 µg/mL
34124/1	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/mL
34124/2	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/mL
34124/3	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/mL
34124/4	LOWENSTEIN JENSEN+PYRAZINAMIDE 200 µg/mL
34125/1	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
34125/2	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/mL
34125/3	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/mL
34125/4	LOWENSTEIN JENSEN + STREPTOMYCIN 2 µg/mL
34125/5	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/mL

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34126/1	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
34126/2	LOWENSTEIN JENSEN + ETHAMBUTOL 4 µg/mL
34126/3	LOWENSTEIN JENSEN + ETHAMBUTOL 5 µg/mL
34126/4	LOWENSTEIN JENSEN + ETHAMBUTOL 1 µg/mL
34126/5	LOWENSTEIN JENSEN + ETHAMBUTOL 3 µg/mL
34126/6	LOWENSTEIN JENSEN + ETHAMBUTOL 10 µg/mL
34127	LOWENSTEIN JENSEN + AMIKACIN 5 µg/mL
34127/1	LOWENSTEIN JENSEN + AMIKACIN 40 µg/mL
34128/1	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/mL
34128/2	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/mL
34128/3	LOWENSTEIN JENSEN + OFLOXACIN 25 µg/mL
34128/4	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/mL
34128/5	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/mL
34129/1	LOWENSTEIN JENSEN + PAS 1 µg/mL
34129/2	LOWENSTEIN JENSEN + PAS 10 µg/mL
34129/3	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
34129/4	LOWENSTEIN JENSEN + PAS 0.1 µg/mL
34129/5	LOWENSTEIN JENSEN + PAS 5 µg/mL
34130/1	LOWENSTEIN JENSEN + RIFABUTIN 10 µg/mL
34130/2	LOWENSTEIN JENSEN + RIFABUTIN 30 µg/mL
34130/3	LOWENSTEIN JENSEN + RIFABUTIN 50 µg/mL
34131/1	LOWENSTEIN JENSEN+CLARITHROMICIN 4 µg/mL
34131/2	LOWENSTEIN JENSEN+CLARITHROMYCIN 32 µg/mL
34132/1	LOWENSTEIN JENSEN + ETHIONAMIDE 10 µg/mL
34132/2	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
34132/3	LOWENSTEIN JENSEN + ETHIONAMIDE 30 µg/mL
34132/4	LOWENSTEIN JENSEN + ETHIONAMIDE 40 µg/mL
34135/1	LOWENSTEIN JENSEN + NICOTINAMIDE 10 µg/mL
34135/2	LOWENSTEIN JENSEN + NICOTINAMIDE 20 µg/mL
34135/3	LOWENSTEIN JENSEN + NICOTINAMIDE 30 µg/mL
34136	LOWENSTEIN JENSEN + PEFLOXACIN 2 µg/mL
34137/1	LOWENSTEIN JENSEN + CYCLOSERINE 30 µg/mL
34137/2	LOWENSTEIN JENSEN + CYCLOSERINE 10 µg/mL
34137/3	LOWENSTEIN JENSEN + CYCLOSERINE 20 µg/mL
34137/4	LOWENSTEIN JENSEN + CYCLOSERINE 40 µg/mL
34137/5	LOWENSTEIN JENSEN + CYCLOSERINE 50 µg/mL
34138/1	LOWENSTEIN JENSEN + CAPREOMYCIN 10 µg/mL
34138/2	LOWENSTEIN JENSEN + CAPREOMYCIN 40 µg/mL
34138/3	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/mL
34138/4	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/mL
34139/1	LOWENSTEIN JENSEN + CLOFAZIMINE 5 µg/mL
34139/2	LOWENSTEIN JENSEN + CLOFAZIMINE 10 µg/mL
34143/1	LOWENSTEIN JENSEN + KANAMYCIN 10 µg/mL
34143/2	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
34143/3	LOWENSTEIN JENSEN + KANAMYCIN 30 µg/mL
34144	LOWENSTEIN JENSEN + PYRUVATE 0.2%
34145	LOWENSTEIN JENSEN + PACT
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml
35000	LOWENSTEIN JENSEN MEDIUM
35001	LOWENSTEIN JENSEN + ISONIAZID 0.20 µg/mL
35002	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml
35010	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
35011	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
35020	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
35021	LOWENSTEIN JENSEN + STREPTOMYCIN 10µg/ml
35030	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
35040	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
35041	LOWENSTEIN JENSEN + ETHIONAMIDE 30µg/ml
35050	LOWENSTEIN JENSEN + PYRAZINAMIDE 1 µg/mL
35060	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL

35061	LOWENSTEIN JENSEN + KANAMYCIN 30µg/ml
35070	LOWENSTEIN JENSEN + PAS 1 µg/mL
35071	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
35080	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/ml
35081	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml
35082	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml
35090	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/ml
35091	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/ml
35147	LOWENSTEIN JENSEN + PNB 500 µg/ml
35148	LOWENSTEIN JENSEN + TCH 2 µg/ml
36001/1	IUTM + STREPTOMYCIN 2 µg/mL
36001/2	IUTM + STREPTOMYCIN 4 µg/mL
36001/3	IUTM + STREPTOMYCIN 10 µg/mL
36001/4	IUTM + STREPTOMYCIN 25 µg/mL
36001/5	IUTM + STREPTOMYCIN 50 µg/mL
36002/1	IUTM + ISONIAZID 0.1 µg/mL
36002/2	IUTM + ISONIAZID 0.2 µg/mL
36002/3	IUTM + ISONIAZID 1 µg/mL
36002/4	IUTM + ISONIAZID 5 µg/mL
36002/5	IUTM + ISONIAZID 10 µg/mL
36003/1	IUTM + ETHAMBUTOL 1 µg/mL
36003/2	IUTM + ETHAMBUTOL 2 µg/mL
36003/3	IUTM + ETHAMBUTOL 3 µg/mL
36003/4	IUTM + ETHAMBUTOL 5 µg/mL
36003/5	IUTM + ETHAMBUTOL 10 µg/mL
36004/1	IUTM + RIFAMPICIN 5 µg/mL
36004/2	IUTM + RIFAMPICIN 10 µg/mL I
36004/3	IUTM + RIFAMPICIN 20 µg/mL
36004/4	IUTM + RIFAMPICIN 40 µg/mL
36004/5	IUTM + RIFAMPICIN 50 µg/mL
36005/1	IUTM + RIFABUTIN 10 µg/mL
36005/2	IUTM + RIFABUTIN 20 µg/mL
36005/3	IUTM + RIFABUTIN 30 µg/mL
36005/4	IUTM + RIFABUTIN 40 µg/mL
36005/5	IUTM + RIFABUTIN 50 µg/mL
36006/1	IUTM + CYCLOSERINE 10 µg/mL
36006/2	IUTM + CYCLOSERINE 20 µg/mL
36006/3	IUTM + CYCLOSERINE 30 µg/mL
36006/4	IUTM + CYCLOSERINE 40 µg/mL
36006/5	IUTM + CYCLOSERINE 50 µg/mL
36007/1	IUTM + OFLOXACIN 1.25 µg/mL
36007/2	IUTM + OFLOXACIN 2.5 µg/mL
36007/3	IUTM + OFLOXACIN 10 µg/mL
36007/4	IUTM + OFLOXACIN 25 µg/mL
36007/5	IUTM + OFLOXACIN 50 µg/mL
36008/1	IUTM + PAS 0.1 µg/mL
36008/2	IUTM + PAS 0.5 µg/mL
36008/3	IUTM + PAS 1 µg/mL
36008/4	IUTM + PAS 5 µg/mL
36008/5	IUTM + PAS 10 µg/mL
36009/1	IUTM + PYRAZINAMIDE 10 µg/mL
36009/2	IUTM + PYRAZINAMIDE 30 µg/mL
36009/3	IUTM + PYRAZINAMIDE 50 µg/mL
36009/4	IUTM + PYRAZINAMIDE 70 µg/mL
36009/5	IUTM + PYRAZINAMIDE 90 µg/mL
37000	MIDDLEBROOK 7H11
37001	MIDDLEBROOK 7H11 + AMIKACIN 2 µg/mL
37002	MIDDLEBROOK 7H11 + AMIKACIN 4 µg/mL
37006	MIDDLEBROOK 7H11 + ETHAMBUTOL 7.5 µg/mL
37011	MIDDLEBROOK 7H11 + ETHIONAMIDE 10 µg/mL

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37016	MIDDLEBROOK 7H11 + ISONIAZIDE 0.2 µg/mL
37017	MIDDLEBROOK 7H11 + ISONIAZIDE 1 µg/mL
37021	MIDDLEBROOK 7H11 + KANAMYCIN 6 µg/mL
37026	MIDDLEBROOK 7H11 + PAS 8 µg/mL
37031	MIDDLEBROOK 7H11 + PYRAZINAMIDE 25 µg/mL
37036	MIDDLEBROOK 7H11 + RIFABUTIN 1 µg/mL
37037	MIDDLEBROOK 7H11 + RIFABUTIN 0.5 µg/mL
37041	MIDDLEBROOK 7H11 + RIFAMPICIN 1 µg/mL
37046	MIDDLEBROOK 7H11 + STREPTOMYCIN 2 µg/mL
37051	MIDDLEBROOK 7H11 + OFLOXACIN 2 µg/mL
37056	MIDDLEBROOK 7H11 + CYCLOSERINE 30 µg/mL
400020	Fluid Thioglycollate Medium 6 x 100 ml
400120	Fluid Thioglycollate Medium 6 x 300 ml
400220	Fluid Thioglycollate Medium 6 x 1000 ml
401890	BUFFER SOLUTION pH 7 6X100 ml
401930	SPS Agar 6X150 ml
401980	TRYPTONE WATER 6X100 ml
401990	ALKALINE PEPTONE WATER 6X100 ml
402000	NUTRIENT BROTH 6X100 ml
402020	MUELLER HINTON II BROTH 6X100 ml
402030	MULLER KAUFFMANN BROTH 6X100 ml
402040	SABOURAUD BROTH 6X100 ml
402050	Selenite Broth 6X100 ml
402060	SALMONELLA DIFF.BROTH 6X90 ml
402070	TRYPTOSE BROTH 6X100 ml
402120	MRS AGAR 6X100 ml
402130	PEPTONE WATER 6X100 ml
402140	BLOOD AGAR BASE 6X100 ml
402170	AZIDE BLOOD AGAR BASE 6X100 ml
402180	CLED AGAR 6X100 ml
402190	NUTRIENT AGAR 6X100 ml
402200	DERMATHOPHYTE (D.T.M.) AGAR 6X100 ml
402210	COLUMBIA CNA AGAR BASE 6X100 ml
402220	DRIGALSKI LACTOSE AGAR 6X100 ml
402230	HEKTOEN ENTERIC AGAR 6X100 ml
402240	MAC CONKEY AGAR 6X100 ml
402250	MUELLER HINTON II AGAR 6X100 ml
402270	PSEUDOMONAS CETRIMIDE AGAR 6X100 ml
402280	SABOURAUD AGAR 6X100 ml
402290	MANNITOL SALT AGAR 6X100 ml
402300	S.S. AGAR 6X100 ml
402320	TRYPTOSE AGAR 6X100 ml
402330	BRILLIANT GREEN AGAR 6X100 ml
402340	DESOXYCHOLATE AGAR 6X100 ml
402350	E.M.B. LEVINE AGAR 6X100 ml
402360	SALMONELLA RAPID TEST 6X100 ml
402370	SABOURAUD CAF AGAR 6X100 ml
402380	BRAIN HEART INFUSION AGAR 6X100 ml
402430	PEPTONE DILUTIONS 6X100 ml
402450	MAC CONKEY SORBITOL AGAR 6X100 ml
402500	Fluid Thioglycollate Medium + 1% Tween 80
402570	X.L.D. AGAR 6X100 ml
403030	BIOTONE BROTH 6X100 ml
403050	S.I.M. MEDIUM 6X100 ml
403060	UREA INDOLE BROTH 6X100 ml
412010	BRAIN HEART INFUSION BROTH 6X200 ml
412030	SIMMONS CITRATE AGAR 6X200 ml
412040	LYSINE IRON AGAR 6X200 ml
412050	Selenite Broth 6X200 ml
412060	TODD HEWITT BROTH 6X200 ml

412080	TRICHOMONAS BROTH 6X200 ml
412100	CHRISTENSEN UREA AGAR 5X200 ml
412110	TRYPTIC SOY BROTH + TWEEN80 1% 6x200ml
412130	PSEUDOMONAS AGAR BASE 6x200ml
412150	AZIDE BLOOD AGAR BASE 6X200 ml
412170	PHENILALANINE AGAR 6X200 ml
412180	CLED AGAR 6X200 ml
412190	NUTRIENT AGAR 6X200 ml
412210	COLUMBIA CNA AGAR BASE 6X200 ml
412230	HEKTOEN ENTERIC AGAR 6X200 ml
412240	MAC CONKEY AGAR 6X200 ml
412250	MUELLER HINTON II AGAR 6X200 ml
412270	PSEUDOMONAS CETRIMIDE AGAR 6X200 ml
412280	SABOURAUD AGAR 6X200 ml
412290	MANNITOL SALT AGAR 6X200 ml
412300	S.S. AGAR 6X200 ml
412370	SABOURAUD CAF AGAR 6X200 ml
413010	ISOSENSITEST AGAR 6X200 ml
413030	CAMPYLOBACTER AGAR 6X200 ml
413040	CLOSTRIDIUM AGAR BASE 6X200 ml
413080	NUTRIENT AGAR acc. to ISO 6579
414010	PEPTONE WATER pH 8.4 + NaCl 1% 6X225 ml
432050	SELENITE BROTH (DOUBLE CONCENT.) 6X200ml
432080	TRYPTIC SOY BROTH 6X225 ml
432250	D-Nase TEST AGAR 6X200 ml
432290	TRYPTIC SOY AGAR 6X200 ml
442080	TRYPTIC SOY BROTH 6X200 ml
442220	Chocolate Agar 6x 100 ml
442280	SABOURAUD MODIFIED AGAR 6X100 ml
442290	TRYPTIC SOY AGAR 6X100 ml
442300	WURTZ LACTOSE AGAR 6X100 ml
442320	BILE AESCULIN AGAR 6X100 ml
442350	BIGGY (NICKERSON) AGAR 6X100 ml
442490	SPS AGAR 6X100 ml
452060	Fluid Thioglycollate Medium 6 x 100 ml
452080	TRYPTIC SOY BROTH 6X100 ml
452210	COLUMBIA AGAR BASE 6X200 ml
452500	Fluid Thioglycollate Medium + 1% Tween 80 25 x 100 ml
453060	Fluid Thioglycollate Medium 25 x 100 ml
463100	Fluid Thioglycollate Medium 6 x 900 ml
463130	Selenite Broth 6X1000 ml
470010	TRYPTIC SOY AGAR 6X500 ml
470020	Selenite Broth 6X500 ml
470030	DESOXYCHOLATE AGAR 6X500 ml
470040	SABOURAUD AGAR 6X500 ml
470050	NUTRIENT BROTH 6X500 ml
470060	NUTRIENT AGAR 6X500 ml
470070	Mueller Hinton II Agar 6X500 ml
470080	MANNITOL SALT AGAR 6X500 ml
470090	MAC CONKEY AGAR 6X500 ml
470100	COLUMBIA AGAR BASE 6X500 ml
470110	CLED AGAR 6X500 ml
470120	Chocolate Agar 6 x 500 ml
470130	BLOOD AGAR BASE 6X500 ml
470140	BILE AESCULIN AGAR 6X500 ml
470150	TRICHOMONAS BROTH 6X500 ml
470160	DESOXYCHOLATE CITRATE AGAR 6X500 ml
470210	ALKALINE PEPTONE WATER 6X500 ml
470220	CZAPEK DOX AGAR 6X500 ml
470280	DRIGALSKI LACTOSE AGAR 6X500 ml

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470290	CARY BLAIR TRANSPORT MEDIUM 6X500 ml
470300	Fluid Thioglycollate Medium 6 x 500 ml
470320	PEPTONE WATER 6X500 ml
470370	TRYPTIC SOY BROTH 6 x 500 ml
471070	SABOURAUD BROTH 6X500 ml
471120	PHYSIOLOGICAL SOLUTION 6X240 ml
473000	PHYSIOLOGICAL SOLUTION 6X500 ml
481110	CHROMATIC™ CANDIDA 6X100 ml
481130	CHROMATIC™ DETECTION 6X100 ml
481140	CHROMATIC™ SALMONELLA 6X100 ml
481160	CHROMATIC™ STAPH AUREUS 6X100 ml
481180	CHROMATIC™ STREP B 6X100ml
482190	Chromatic™ E.coli O157 6 x 200 ml
490010	HEMO-AEROBIC culturing 6X80 ml
490020	HEMO-ANAEROBIC culturing 6X80 ml
490030	HEMO-AEROBIC culturing-Pediatric 6X40 ml
490040	HEMO-ANAEROBIC culturing-Pediatric 6X40ml
490050	HEMO-AEROBIC culturing NEONATAL 6x9 ml
490060	HEMO-ANAEROBIC culturing NEONATAL 6x9 ml
493000	Fluid Thioglycollate Medium 6 x 100 ml
495010	TRYPTIC SOY BROTH 6x100 ml
495020	Fluid Thioglycollate Medium 6 x 100 ml
500142	URITEST PENTA
500152	URITEST
500182	URITEST M
500702	URITEST EF
50020	VAGITEST
50021	DERMATEST
500232	URITEST N
500302	URITEST 2
500402	URITEST MALTO
500412	URITEST EC
51014	URITEST PENTA
51015	URITEST
51018	URITEST M
51020	VAGITEST 120 slide
51021	DERMATEST
51023	URITEST N
51024	URITEST C
51030	URITEST 2
51040	URITEST MALTO
51041	URITEST EC
51070	URITEST EF
51118	URITEST M
51123	URITEST N 500 slide
51130	URITEST 2 500 slide
51140	URITEST MALTO
51170	CLED/MAC CONKEY/ BILE AESCULIN
52115	CLED/MAC CONKEY/SLANETZ 120 slide
52119	URITEST SF 500 slide
610001	BILE AESCULIN AZIDE AGAR
610002	DEXTROSE AGAR
610005	BLOOD AGAR BASE
610006	BORDET GENGOU AGAR BASE
610007	BRAIN HEART INFUSION AGAR
610008	BRAIN HEART INFUSION BROTH
6100085	BRAIN HEART INFUSION BROTH
610009	BRILLIANT GREEN AGAR
610012	CLED AGAR
6100125	CLED AGAR

610013	COLUMBIA AGAR BASE
6100135	COLUMBIA AGAR BASE
610014	DESOXYCHOLATE AGAR
6100145	DESOXYCHOLATE AGAR
610015	DESOXYCHOLATE CITRATE AGAR
610016	DRIGALSKI LACTOSE AGAR
610019	E.M.B. LEVINE AGAR
610021	HEKTOEN ENTERIC AGAR
6100215	HEKTOEN ENTERIC AGAR
610022	G.C. MEDIUM
610023	KLIGLER IRON AGAR
610024	M.R.S. AGAR (ISO/FDIS 15214)
610025	M.R.S. BROTH (ISO/FDIS 15214)
610026	LOWENSTEIN JENSEN MEDIUM
6100265	LOWENSTEIN JENSEN MEDIUM
610027	LYSINE IRON AGAR
610028	MAC CONKEY AGAR
6100285	MAC CONKEY AGAR
610029	MANNITOL SALT AGAR
6100295	MANNITOL SALT AGAR
610032	MR-VP BROTH
610033	MUELLER HINTON AGAR
6100335	MUELLER HINTON AGAR
610034	MUELLER HINTON BROTH
610035	MULLER KAUFFMANN BROTH
610036	NUTRIENT AGAR
610037	NUTRIENT BROTH
6100375	NUTRIENT BROTH
610038	PEPTONE WATER
610039	PHENYLALANINE AGAR
610041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
6100415	PSEUDOMONAS CETRIMIDE AGAR
610042	SS AGAR (MODIFIED)
6100425	SS AGAR (MODIFIED)
610043	SCHAEDLER AGAR BASE
610044	PURPLE LACTOSE AGAR
610046	SIMMONS CITRATE AGAR
610047	MONSUR AGAR
610048	AEROMONAS AGAR BASE
610049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
610050	Fluid Thioglycollate Medium
6100505	Fluid Thioglycollate Medium
610051	TODD HEWITT BROTH
6100515	TODD HEWITT BROTH
610052	TRYPTIC SOY AGAR
6100525	TRYPTIC SOY AGAR (Harm.EP) 5 KG
610053	TRYPTIC SOY BROTH
6100535	TRYPTIC SOY BROTH
610055	T.S.I. AGAR USP
610056	CLOSTRIDIUM BROTH
6100565	CLOSTRIDIUM BROTH
610057	MAC CONKEY AGAR No.2
6100575	MAC CONKEY AGAR No.2 5 KG
610060	X.L.D. AGAR (ISO 6579)
6100605	X.L.D. AGAR
610061	TRICHOMONAS BROTH
610065	GSB AGAR BASE (ISLAM)
610070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
6100705	YEAST GLUCOSE CHLORAMPHENICOL AGAR 5 Kg
610071	PSEUDOMONAS AGAR BASE

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610072	CZAPEK DOX BROTH
610074	TRYPTONE SULFITE NEOMYCIN AGAR
610075	PHENYLALANINE MALONATE BROTH
610079	BRUCELLA AGAR BASE
610080	WORT BROTH W/O NaCl
610092	XLT 4 AGAR
610095	CZAPEK DOX AGAR
610096	REINFORCED CLOSTRIDIAL AGAR
610097	STAPHYLOCOCCUS BROTH
610098	ALKALINE PEPTONE WATER
610101	MALT AGAR
610103	SABOURAUD AGAR
6101035	SABOURAUD AGAR
610104	SABOURAUD BROTH
610107	UREA AGAR BASE (ISO 6785)
610108	MAC CONKEY SORBITOL AGAR
610109	P.P.L.O. BROTH
610110	MUELLER HINTON AGAR MODIFIED
610111	YERSINIA SELECTIVE AGAR BASE
610112	CLED ANDRADE AGAR
610113	COLUMBIA CNA AGAR BASE
610114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
610115	CLOSTRIDIUM DIFFICILE AGAR BASE
610117	TRYPTONE YEAST AGAR
610118	ANDRADE LACTOSE PEPTONE WATER
610123	CORN MEAL AGAR
610125	LEGIONELLA CYE AGAR BASE
610128	MAC CONKEY AGAR w/o BILE SALT
610130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
610131	CAMPYLOBACTER ENRICHMENT BROTH BASE
610132	MOTILITY TEST AGAR
610134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
610135	BIGGY (NICKERSON) AGAR
610136	BACILLUS CEREUS AGAR BASE (PEMBA)
610137	SCHAEDLER BROTH
610140	E.M.B. AGAR w LACTOSE + SUCROSE
610143	LIVER BROTH
610144	MRS BROTH w/o GLUCOSE
610145	SELENITE BROTH
6101455	SELENITE BROTH
610146	SABOURAUD MALTOSE AGAR
610147	SLANETZ AND BARTLEY AGAR + TTC
6101475	SLANETZ AND BARTLEY AGAR + TTC
610148	SPS AGAR
610151	BILE AESCULIN BROTH
610152	AMIES TRANSPORT MEDIUM + CHARC.
6101525	AMIES TRANSPORT MEDIUM + CHARC.
610153	AZIDE BLOOD AGAR BASE
610155	AZIDE VIOLET BLOOD AGAR BASE
610157	BIOTONE AGAR
610158	BIOTONE BROTH
610159	CPLM SELECTIVE WITH CAF
610160	DERMATOPHYTE (D.T.M.) AGAR
610161	DEXTROSE BROTH
610163	G.N. HAJNA BROTH
610164	HERELLEA AGAR
6101645	HERELLEA AGAR
610165	KOSER CITRATE MEDIUM
610168	LISTERIA PALCAM AGAR
610169	I.U.T.M. MEDIUM

610170	MAC CONKEY MMG AGAR
6101705	MAC CONKEY MMG AGAR
610172	MALONATE BROTH
610174	PHENOL RED BROTH BASE
610175	RAPPAPORT VASSILIADIS BROTH (ISO 6785-6579)
610176	ROGOSA AGAR
610177	ROGOSA BROTH
610179	SABOURAUD CAF AGAR + ACTIDIONE
610180	S.F. BROTH
610181	S.I.M. MEDIUM
610182	STUART TRANSPORT MEDIUM
610183	TETRATHIONATE BROTH BASE
610185	TRYPTIC (CTA) MEDIUM
610186	VOGEL JOHNSON AGAR
610188	BLOOD AGAR BASE N. 2
610191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
6101915	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
610193	TRYPTOSE AGAR
610195	MAC CONKEY AGAR w/o CRYSTAL VIOLET
610196	TRYPTIC BILE AGAR
610197	TRYPTOFAN BROTH
610200	CAMPYLOBACTER KARMALI AGAR BASE
610203	SABOURAUD CAF AGAR
6102035	SABOURAUD CAF AGAR 5 KG
610205	DNase TEST AGAR
610206	TRYPTONE WATER (ISO/DIS 3811)
610207	CLOSTRIDIUM PERFRINGENS AGAR BASE
610210	BILE AESCULIN AGAR
610211	KLIGLER IRON AGAR MOD.
610214	MIDDLEBROOK 7H9 BROTH BASE
610217	NUTRIENT BROTH N.2
610218	Mueller Hinton II Broth
610221	ANTIBIOTIC TEST MEDIUM
610222	CLOSTRIDIUM BROTH w/o AGAR
6102225	CLOSTRIDIUM BROTH w/o AGAR
610223	MAC CONKEY AGAR w/o Salt
610227	PHENOL RED AGAR BASE
610229	ANTIBIOTIC MEDIUM E
610230	OXIDATIVE/FERMENTATIVE MEDIUM
610233	TRYPTOSE BROTH
610235	MANNITOL MOTILITY TEST MEDIUM
610236	MOTILITY INDOLE UREA AGAR (M.I.U.)
610241	TRYPTONE SOYA YEAST EXTRACT BROTH
610245	LB AGAR
610301	BISMUTH SULPHITE AGAR
610303	Lysine Decarboxylase Broth
610304	OF BASAL MEDIUM
610305	ORNITHINE DECARBOXYLASE BROTH
610306	ARGININE DECARBOXYLASE BROTH
610308	PHENOL RED AGAR BASE
610309	PSEUDOMONAS AGAR F
610310	PSEUDOMONAS AGAR P
610311	UREA BROTH
610315	ANTIBIOTIC AGAR N.11
610319	PFIZER SELECTIVE ENTEROCOCCUS AGAR
610322	NITRATE BROTH
610331	DIAGNOSTIC SENSITIVITY TEST AGAR (D.S.T.)
610339	T.S.I. AGAR acc.EP
610341	EMGON BROTH
610343	MANNITOL SALT BROTH



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610363	Yeast Extract Sodium Lactate medium
610364	Tryptose Phosphate Broth
6103645	Tryptose Phosphate Broth
610372	Cooked Meat Medium
610492	POLYPEPTONE
610495	BRAIN HEART INFUSION
6104955	BRAIN HEART INFUSION
610496	ACID HYDROLISATE OF CASEIN
610497	BEEF EXTRACT
6104975	BEEF EXTRACT
610498	LACTOSE
6104985	LACTOSE
610506	CYSTINE HEART AGAR
610611	CHROMATIC™ SALMONELLA
610612	CHROMATIC™ DETECTION
6106125	CHROMATIC™ DETECTION
610613	CHROMATIC™ CANDIDA
610614	Chromatic™ E.coli O157
610615	CHROMATIC™ MRSA
610616	CHROMATIC™ STAPH AUREUS
610617	CHROMATIC™ STREP B
610625	SABOURAUD CAF (50 mg/L) AGAR
610627	MUELLER HINTON II AGAR
6106275	MUELLER HINTON II AGAR
610629	CHROMATIC™ ESBL
611000	SODIUM CHLORIDE
611001	AGAR
6110015	AGAR
611002	GELATIN BACTERIOLOGICAL
6110025	GELATIN BACTERIOLOGICAL
611003	SODIUM SELENITE
6110035	SODIUM SELENITE
611004	TRYPTONE
6110045	TRYPTONE
611005	YEAST EXTRACT
6110055	YEAST EXTRACT
611006	MALT EXTRACT
6110065	MALT EXTRACT
611007	CAMPYLOBACTER AGAR BASE
611008	TRYPTOSE
6110085	TRYPTOSE
611009	GLUCOSIO
611010	T.C.B.S. AGAR
611015	SIERRA LIPOLYTIC AGAR
611016	YEAST EXTRACT AGAR (ISO 6222)
611021	HEART INFUSION BROTH
6110215	HEART INFUSION BROTH
611022	MIDDLEBROOK 7H10 AGAR BASE
611203	SABOURAUD CAF (1g/l) AGAR
611210	WURTZ LACTOSE AGAR
611265	ISOSENSITEST AGAR
611366	STAPHYLOCOCCUS 110 AGAR
611367	BILE BACTERIOLOGICAL
611401	IRON SULPHITE AGAR
611402	CARY BLAIR TRANSPORT MEDIUM
611502	CASEIN PEPTONE
611601	GLUCOSE
6116015	GLUCOSE
611618	CHROMATIC™ MH
611619	CHROMATIC™ CRE AGAR BASE

611701	PEPTONE BACTERIOLOGICAL
6117015	PEPTONE BACTERIOLOGICAL
611801	SUCROSE
6118015	SUCROSE
611901	BILE SALT N.3
6119015	BILE SALT N.3
612001	LIVER EXTRACT
6120015	LIVER EXTRACT
612101	PEPTONE MYCOLOGICAL
6121015	PEPTONE MYCOLOGICAL
612201	PROTEOSE PEPTONE
6122015	PROTEOSE PEPTONE
612202	STREPTOCOCCUS SELECTIVE AGAR
612203	STREPTOCOCCUS BROTH
612501	SOY PEPTONE
6125015	SOY PEPTONE
620001	BILE AESCULIN AZIDE AGAR
620002	DEXTROSE AGAR
620005	BLOOD AGAR BASE
620006	BORDET GENGOU AGAR BASE
620007	BRAIN HEART INFUSION AGAR
620008	BRAIN HEART INFUSION BROTH
620009	BRILLIANT GREEN AGAR
620012	CLED AGAR
620013	COLUMBIA AGAR BASE
620014	DESOXYCHOLATE AGAR
620015	DESOXYCHOLATE CITRATE AGAR
620016	DRIGALSKY LACTOSE AGAR
620019	E.M.B. LEVINE AGAR
620021	HEKTOEN ENTERIC AGAR
620022	G.C. MEDIUM
620023	KLIGLER IRON AGAR
620024	M.R.S. AGAR (ISO/FDIS 15214)
620025	M.R.S. BROTH (ISO/FDIS 15214)
620026	LOWENSTEIN JENSEN MEDIUM
620027	LYSINE IRON AGAR
620028	MAC CONKEY AGAR
620029	MANNITOL SALT AGAR
620032	MR-VP BROTH
620033	MUELLER HINTON AGAR
620034	MUELLER HINTON BROTH
620035	MULLER KAUFFMANN BROTH
620036	NUTRIENT AGAR
620037	NUTRIENT BROTH
620038	PEPTONE WATER
620039	PHENYLALANINE AGAR
620041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
620042	SS AGAR (MODIFIED)
620043	SCHAEDLER AGAR BASE
620044	PURPLE LACTOSE AGAR
620046	SIMMONS CITRATE AGAR
620047	MONSUR AGAR
620048	AEROMONAS AGAR BASE
620049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
620050	Fluid Thioglycollate Medium
620051	TODD HEWITT BROTH
620052	TRYPTIC SOY AGAR
620053	TRYPTIC SOY BROTH
620055	T.S.I. AGAR USP
620056	CLOSTRIDIUM BROTH

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620057	MAC CONKEY AGAR No.2
620060	X.L.D. AGAR (ISO 6579)
620061	TRICHOMONAS BROTH
620065	GSB AGAR BASE (ISLAM)
620070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
620071	PSEUDOMONAS AGAR BASE
620072	CZAPEK DOX BROTH
620074	TRYPTONE SULFITE NEOMYCIN AGAR
620075	PHENYLALANINE MALONATE BROTH
620079	BRUCELLA AGAR BASE
620092	XLT 4 AGAR
620095	CZAPEK DOX AGAR
620096	REINFORCED CLOSTRIDIAL AGAR
620097	STAPHYLOCOCCUS BROTH
620098	ALKALINE PEPTONE WATER
620101	MALT AGAR
620103	SABOURAUD AGAR
620104	SABOURAUD BROTH
620107	UREA AGAR BASE (ISO 6785)
620108	MAC CONKEY SORBITOL AGAR
620109	P.P.L.O. BROTH
620110	MUELLER HINTON AGAR MODIFIED
620111	YERSINIA SELECTIVE AGAR BASE
620112	CLED ANDRADE AGAR
620113	COLUMBIA CNA AGAR BASE
620114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
620115	CLOSTRIDIUM DIFFICILE AGAR BASE
620117	TRYPTONE YEAST AGAR
620118	ANDRADE LACTOSE PEPTONE WATER
620122	MIDDLEBROOK 7H10 AGAR BASE
620123	CORN MEAL AGAR
620125	LEGIONELLA CYE AGAR BASE
620130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
620131	CAMPYLOBACTER ENRICHMENT BROTH BASE
620132	MOTILITY TEST AGAR
620134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
620135	BIGGY (NICKERSON) AGAR
620136	BACILLUS CEREUS AGAR BASE (PEMBA)
620137	SCHAEDLER BROTH
620140	E.M.B. AGAR w LACTOSE + SUCROSE
620143	LIVER BROTH
620144	MRS BROTH w/o GLUCOSE
620145	SELENITE BROTH
620146	SABOURAUD MALTOSE AGAR
620147	SLANETZ AND BARTLEY AGAR + TTC
620148	SPS AGAR
620151	BILE AESCULIN BROTH
620152	AMIES TRANSPORT MEDIUM + CHARC.
620153	AZIDE BLOOD AGAR BASE
620155	AZIDE VIOLET BLOOD AGAR BASE
620157	BIOTONE AGAR
620158	BIOTONE BROTH
620159	CPLM SELECTIVE WITHCAF
620160	DERMATOPHYTE (D.T.M.) AGAR
620161	DEXTROSE BROTH
620163	G.N. HAJNA BROTH
620164	HERELLEA AGAR
620165	KOSER CITRATE BROTH
620168	LISTERIA PALCAM AGAR
620169	I.U.T.M. MEDIUM

620170	MAC CONKEY MMG AGAR
620172	MALONATE BROTH
620174	PHENOL RED BROTH BASE
620175	RAPPAPORT VASSILIADIS BROTH
620176	ROGOSA AGAR
620177	ROGOSA BROTH
620179	SABOURAUD CAF AGAR + ACTIDIONE
620180	S.F. BROTH
620181	S.I.M. MEDIUM
620182	STUART TRANSPORT MEDIUM
620183	TETRATHIONATE BROTH BASE
620185	TRYPTIC (CTA) MEDIUM
620186	VOGEL JOHNSON AGAR
620188	BLOOD AGAR BASE N. 2
620191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
620193	TRYPTOSE AGAR
620195	MAC CONKEY AGSAR w/o CRYSTAL VIOLET
620196	TRYPTIC BILE AGAR
620197	TRYPTOFAN BROTH
620200	CAMPYLOBACTER KARMALI AGAR BASE
620203	SABOURAUD CAF AGAR
620205	DNase TEST AGAR
620206	TRYPTONE WATER (ISO/DIS 3811)
620207	CLOSTRIDIUM PERFRIGENS AGAR BASE
620210	BILE AESCULIN AGAR
620211	KLIGLER IRON AGAR MOD.
620214	MIDDLEBROOK 7H9 BROTH BASE
620217	NUTRIENT BROTH N.2
620218	Mueller Hinton II Broth
620227	PHENOL RED AGAR BASE
620229	ANTIBIOTIC MEDIUM E
620233	TRYPTOSE BROTH
620235	MANNITOL MOTILITY TEST MEDIUM
620241	TRYPTONE SOYA YEAST EXTRACT BROTH
620303	Lysine Decarboxylase Broth
620309	PSEUDOMONAS AGAR F
620311	UREA BROTH
620495	BRAIN HEART INFUSION
620496	ACID HYDROLISATE OF CASEIN
620497	BEEF EXTRACT
620498	LACTOSE
620611	CHROMATIC™ SALMONELLA
620612	CHROMATIC™ DETECTION
620613	CHROMATIC™ CANDIDA
620614	Chromatic™ E.coli O157
620615	CHROMATIC™ MRSA
620616	CHROMATIC™ STAPH AUREUS
620617	CHROMATIC™ STREP B
620627	MUELLER HINTON II AGAR
620629	CHROMATIC™ ESBL
621000	SODIUM CHLORIDE
621001	AGAR
621003	SODIUM SELENITE
621004	TRYPTONE
621005	YEAST EXTRACT
621006	MALT EXTRACT
621007	CAMPYLOBACTER AGAR BASE
621010	TCBS AGAR
621015	SIERRA LIPOLYTIC AGAR
621016	YEAST EXTRACT AGAR (ISO 6222)

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621021	HEART INFUSION BROTH
621022	MIDDLEBROOK 7H10 AGAR BASE
621210	WURTZ LACTOSE AGAR
621265	ISOSENSITEST AGAR
621367	BILE BACTERIOLOGICAL
621401	IRON SULPHITE AGAR
621402	CARY BLAIR TRANSPORT MEDIUM
621601	GLUCOSE
621618	CHROMATIC™ MH
621619	CHROMATIC™ CRE AGAR BASE
621701	PEPTONE BACTERIOLOGICAL
622202	STREPTOCOCCUS SELECTIVE AGAR
630026	LOWENSTEIN JENSEN MEDIUM w GLYCEROL 1 litre
71618	ENTEROSYSTEM 18R 20 Tests
71630	STAF SYSTEM 18 R 20 Tests
71670	COPRO SYSTEM 40 Tests
71675	COPRO SYSTEM Plus 20 Tests
71678	PATHOGENIC SYSTEM DOUBLE 40 Tests
71679	PATHOGENIC SYSTEM 20 Tests
71681	PATHOGENIC SYSTEM AST
71714	INTEGRAL SYSTEM ENTEROBATTERI 20 Tests
71718	INTEGRAL SYSTEM STAFILOCOCCI 20 Tests
71720	INTEGRAL SYSTEM STREPTOCOCCI 20 Tests
71724	INTEGRAL SYSTEM GARDNERELLA 20 TESTS
71822	INTEGRAL SYSTEM YEASTS Plus 20 Tests
72560	STREPTO SYSTEM 12 R 40 Tests
72592	MYCOPLASMA SYSTEM Plus 20 Tests
74156	A.F. GENITAL SYSTEM 20 Tests
74160	URIN SYSTEM Plus 20 Tests
74161	URIN SYSTEM Chrom 20 Tests
76010	Sensi Test gram-negative 20 Tests
76020	Sensi Test gram-positive 20 Tests
76031	SensiQuattro Gram-negative 20 Tests
76032	SensiQuattro Gram-positive 20 Tests
76033	SensiQuattro Candida EU 20 Tests
78618	ENTERO PLURI TEST 10 Tests
78619	ENTERO PLURI TEST 25 Tests
78620	OXI/FERM PLURI TEST 10 Tests
78621	OXI/FERM PLURI TEST 25 Tests
79010	Sensi Test gram-negative 4 Tests
79020	Sensi Test gram-positive 4 Tests
79031	SensiQuattro Gram-negative 4 Tests
79032	SensiQuattro Gram-positive 4 Tests
79033	SensiQuattro Candida EU 4 Tests
79156	A.F. GENITAL SYSTEM 4 Tests
79160	URIN SYSTEM Plus 4 Tests
79161	URIN SYSTEM Chrom 4 Tests
79560	STREPTO SYSTEM 12 R 8 Tests
79592	MYCOPLASMA SYSTEM Plus 4 Tests
79618	ENTEROSYSTEM 18R 4 Tests
79630	STAF SYSTEM 18 R 4 Tests
79670	COPRO SYSTEM 8 Tests
79675	COPRO SYSTEM Plus 4 Tests
79678	PATHOGENIC SYSTEM DOUBLE 8 Tests
79679	PATHOGENIC SYSTEM 4 Tests
79681	PATHOGENIC SYSTEM AST
79714	INTEGRAL SYSTEM ENTEROBATTERI 4 Tests
79718	INTEGRAL SYSTEM STAFILOCOCCI 4 Tests
79720	INTEGRAL SYSTEM STREPTOCOCCI 4 Tests
79724	INTEGRAL SYSTEM GARDNERELLA 4 Tests

79822	INTEGRAL SYSTEM YEASTS Plus 4 Tests
80009	IODINE MKTT SOLUTION 10 x 10 ml
80010	XLT 4 supplement 2 x 50 ml
80021	GLYCEROL supplement 4 x 50 ml
80022	POTASSIUM TELLURITE 1% suppl. 5 x 10 ml
80031	TWEEN 80 supplement 2 x 50 ml
80040	CHROMATIC™ SALMONELLA Supplement 2x50 ml
80047	MULLER KAUFFMANN 3X50 ml (Iodio/B.G.O.1%)
80053	VITAMIN K 1% supplement 5 x 5 ml
80056	LEGIONELLA growth supplement 10 vials
80057	H2O2 REAGENT 1 x 10 ml
80060	DECONTAM-KIT
80110	UREA 40% 6X100 ml
80219	EGG YOLK emulsion 4 x 50 ml
80252	ENTEROSYSTEM 18R REAGENT 100/200 Tests
80253	COPRO SYSTEM REAGENTS (antisera)
80257	LISTERIA SYSTEM 18R -REAG 100/200 Tests
80258	AF GENITAL SYSTEM REAGENT
80260	IDENTIF. SYSTEM-REAGENT 100/200 Tests
80271	KOVAC'S REAGENT 4x25 ml
80272	FERRIC CHLORIDE 10% 2x 25 ml
80273	NINHYDRIN 7% 10 ml
80275	MIF COLOR KIT 50 Tests
80276	ZIEHL-NEELEN 3 x 250 ml
80277	METHYLENE BLUE Solution 250 ml
80279	VASELINE OIL 4 x 50 ml
80280	V.P. TEST-Reagent 10x10ml
80281	V.P. TEST EP 10 x 10 mL
80282	Kit May-Grünwald Giemsa
80290	SAFRANIN SOLUTION 1000 ml
80291	POTASSIUM TELLURITE 3.5% suppl.5x10 ml
80292	UREA 40 % supplement 10 x 5 ml
80293	GRAM COLOR KIT 4 x 250 ml
80294	KIT COLOR ALBERT 2 x 250 ml
80295	DECOLOURIZING SOLUTION 1000 ml
80296	LUGOL PVP SOLUTION 1000 ML
80297	SAFRANIN SOLUTION 500 ml
80298	LUGOL PVP SOLUTION 250 ml
80299	CRYSTAL VIOLET SOLUTION 1000 ml
80300	TTC 1% supplement 5 x 10 ml
80350	ANTIBIOTIC TEST
80351	RAPID ANTIBIOTIC TEST 50 Tests
80380	KINYOUN COLOR KIT 2 x 250 ml
80390	FIXUR 1
80409	IODINE SOLUTION 10 x 10 ml
80410	XLT 4 SUPPLEMENT 4 x 50 ml
80422	POTASSIUM TELLURITE 1% Supplement 10 x 10 ml
80430	TTC 1% supplement 10 x 10 ml
80431	TWEEN 80 Supplement 4 x 50 ml
80453	VITAMIN K 1% SUPPLEMENT 10 x 5 ml
80491	POTASSIUM TELLURITE 3.5% Supplement 10 x 10
81001	AMPICILLIN supplement 10 vials
81002	LEGIONELLA (BMPA) supplement 10 vials
81003	BRUCELLA supplement 10 vials
81004	CAMPYLOBACTER Preston supplem 10 vials
81006	CN (Pseudomonas) supplement 10 vials
81007	CLOSTRIDIUM difficile suppleme 10 vials
81008	LEGIONELLA (GVPC) supplement 10 vials
81009	IODINE solution 5 x 10 ml
81011	CLOSTRIDIUM perfringens (T.S.C.) sup.10 v.

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81012	LCAT supplement 10 vials
81013	BORDETELLA supplement 10 vials
81014	HAEMOPHILUS supplement 10 vials
81015	CAMPYLOBACTER Butzler supplement 10 vials
81016	BACILLUS Cereus Supplement 10 Vials
81017	CHLORAMPHENICOL supplement 10 vials
81019	LEGIONELLA (MWY) supplement 10 vials
81020	MMG Supplement 10 vials
81022	V.C.N. supplement 10 vials
81023	VITALEX growth supplement 10 vials
81024	V.C.N.T. supplement 10 vials
81025	DERMATOPHYTE supplement 10 vials
81026	LISTERIA PALCAM supplement 10 vials
81032	ONPG 1.5% Supplement 10 vials
81033	GENTAMYCIN supplement 10 vials
81035	MIDDLEBROOK 7H 10 supplement 4 x 50 ml
81036	CAMPYLOBACTER KARMALI Supplement 10 vials
81037	CAMPYLOBACTER CGDA supplement 10 vials
81038	CAMPYLOBACTER C.T.V.N. Supplement 10 vials
81039	YERSINIA supplement 10 vials
81040	GARDNERELLA vaginalis Supplement 10vials
81041	V.C.A.T. supplement 10 vials
81042	LISTERIA FRASER supplement (1125mg)10 vials
81048	CNA (Staf/Strep) supplement 10 vials
81050	CAMPYLOBACTER growth supplement 10 vials
81051	CAMPYLOBACTER Blaser Wang supp 10 vials
81054	SCHAEDLER supplement 10 vials
81055	CAMPYLOBACTER Skirrow suppl 10 vials
81056	LEGIONELLA (BCYE) growth suppl.10 vials
81062	VANCOMYCIN Supplement for VRE 10 vials
81077	CAMPYLOBACTER C.T.V.A. Supplement 10 vials
81078	CHROMATIC™ MRSA Supplement
81079	UREA-ARGININE SCREEN
81082	CEFIXIME TELLURITE Supplement
81083	MEROPENEM Supplement
81084	NEOMYCIN Solution
81085	CHROMATIC™ STAPH AUREUS Supplement
81086	VCC MOD SELECTIVE Supplement
81088	CHROMATIC™ CRE Supplement
81089	Chromatic™ ESBL Supplement
81090	CHROMATIC™ ESBL+AmpC Supplement
81091	Legionella BCYE Growth Supplement w/o L-Cysteine
83810	HORSE SERUM 1 x 100 ml
85501	COPRO KIT (SELENITE BROTH)
85502	COPRO KIT 2 (SALMONELLA BROTH)
87001	KOVAC'S Reagent
87002	VP (NaOH) Reagent
87003	CATALASE Reagent
87004	PHENYLALANINE Reagent
87005	OXIDASE Reagent
87006	Vaseline Oil
87007	VP (KOH) Reagent
87008	Lactophenol Cotton Blue Droppers
87101	GRAM COLOR KIT
88001	BETA LACTAMASE TEST 30 Tests
88003	OXIDASE TEST SWABS 30 Tests
88004	OXIDASE TEST DISCS 30 Discs
88005	O.N.P.G. TEST 30 Tests
88006	E. COLI TEST 30 Tests
88007	HIPPURATE TEST 30 Tests

88008	AESCULIN BILE TEST 30 Tests
88009	NITRATI TEST 30 Tests 30 Tests
88010	LISTERIA MONO TEST 20 Tests
88011	UREA RAPID TEST 30 Tests
88013	H2S RAPID TEST 30 Tests
88014	LYSINE DECARBOXYLASE TEST 30 Tests
88015	ORNITHINE DECARBOXYLASE TEST 30 Tests
88016	ARGININE DECARBOXYLASE TEST 30 Tests
88017	INDOLE TEST 30 Tests
88020	S F RAPID TEST 30 Tests
88021	CAMP TEST-S 30 Tests
88023	CATALASI/OXY TEST 30 Tests
88024	UREA / INDOLO TEST 30 Tests
88027	CAMP TEST-R 30 Tests
88028	PEPTIDASE A TEST 30 Tests
88029	OXIDASE TEST STICKS 50 Tests
88030	COAGULASE TEST 40 Tests
88031	GRAM TEST STICK 30 Tests
88032	INDOLO TEST STICK 30 Tests
88033	BETA LACTAMASE STICKS 30 Tests
88034	PEPTIDASE A STICKS 30 Tests
88035	VP TEST KIT
88040	C 390 50 Discs
88041	Brilliant Green 100 µg
88042	CITRATE TEST
88043	O129 Disc 150 µg
88044	O129 Disc 10 µg
88105	O.N.P.G. TEST
88201	GALACTOSE TEST 30 Tests
88202	GLUCOSE TEST 30 Tests
88203	LACTOSE TEST 30 Tests
88204	MALTOSE TEST 30 Tests
88205	RAFFINOSE TEST 30 Tests
88206	SUCROSE TEST 30 Tests
88207	ARABITOL TEST 30 Tests
88208	ADONITOL TEST 30 Tests
88209	ARABINOSE TEST 30 Tests
88210	DULCITOL TEST 30 Tests
88211	INOSITOL TEST 30 Tests
88212	INULIN TEST 30 Tests
88213	LEVULOSE TEST 30 Tests
88214	MANNITOL TEST 30 Tests
88215	MANNOSE TEST 30 Tests
88216	RHAMNOSE TEST 30 Tests
88217	SALICIN TEST 30 Tests
88218	SORBITOL TEST 30 Tests
88219	TREHALOSE TEST 30 Tests
88220	XYLOSE TEST 30 Tests
89021	CultiControl™ Aspergillus brasiliensis ATCC® 16404™
89022	CultiControl™ Bacillus Cereus ATCC® 11778™
89023	CultiControl™ Bacillus subtilis ATCC® 6633™
89024	CultiControl™ Candida albicans ATCC® 10231™
89025	CultiControl™ Enterococcus faecalis ATCC® 19433™
89026	CultiControl™ Enterococcus faecalis ATCC® 29212™
89027	CultiControl™ Escherichia coli ATCC® 25922™
89028	CultiControl™ Escherichia coli ATCC® 8739™
89029	CultiControl™ Listeria innocua ATCC® 33090™
89030	CultiControl™ Listeria ivanovii ATCC® 19119™
89031	CultiControl™ Listeria monocytogenes ATCC® 19111™
89032	CultiControl™ Proteus mirabilis ATCC® 25933™

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89033	CultiControl™ <i>Pseudomonas aeruginosa</i> ATCC® 27853™
89034	CultiControl™ <i>Pseudomonas aeruginosa</i> ATCC® 9027™
89035	CultiControl™ <i>Rhodococcus equi</i> ATCC® 6939™
89036	CultiControl™ <i>Saccharomyces cerevisiae</i> ATCC® 9763™
89037	CultiControl™ <i>Salmonella typhimurium</i> ATCC® 14028™
89038	CultiControl™ <i>Shigella flexneri</i> ATCC® 12022™
89039	CultiControl™ <i>Staphylococcus aureus</i> NCTC 12493
89040	CultiControl™ <i>Staphylococcus aureus</i> ATCC® 25923™
89041	CultiControl™ <i>Staphylococcus aureus</i> ATCC® 29213™
89042	CultiControl™ <i>Staphylococcus aureus</i> ATCC® 33862™
89043	CultiControl™ <i>Staphylococcus aureus</i> ATCC® 43300™
89044	CultiControl™ <i>Staphylococcus aureus</i> ATCC® 6538™
89045	CultiControl™ <i>Staphylococcus epidermidis</i> ATCC® 12228™
89046	CultiControl™ <i>Streptococcus agalactiae</i> ATCC® 13813™
89047	CultiControl™ <i>Streptococcus pneumoniae</i> ATCC® 49619™
89048	CultiControl™ <i>Streptococcus pyogenes</i> ATCC® 19615™
89049	CultiControl™ <i>Proteus mirabilis</i> ATCC® 12453™
89050	CultiControl™ <i>Yersinia enterocolitica</i> ATCC® 9610™
89051	CultiControl™ <i>Listeria monocytogenes</i> ATCC® 19115™
89052	CultiControl™ <i>Legionella pneumophila</i> subsp. <i>pneumophila</i> ATCC® 33152™
89053	CultiControl™ <i>Clostridium perfringens</i> ATCC® 13124™
89054	CultiControl™ <i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhimurium</i> ATCC® 13311™
89055	CultiControl™ <i>Lactobacillus paracasei</i> subsp. <i>paracasei</i> ATCC ® BAA-52™
89056	CultiControl™ <i>Vibrio parahaemolyticus</i> ATCC ® 17802™
89057	CultiControl™ <i>Aspergillus fumigatus</i> ATCC ® 204305™
89058	CultiControl™ <i>Shigella sonnei</i> ATCC ® 25931™
89059	CultiControl™ <i>Clostridium sordellii</i> ATCC ® 9714™
89060	CultiControl™ <i>Listeria monocytogenes</i> ATCC ® 7644™
89061	CultiControl™ <i>Streptococcus bovis</i> ATCC ® 33317™
89062	CultiControl™ <i>Streptococcus mutans</i> ATCC ® 25175™
89063	CultiControl™ <i>Streptococcus pneumoniae</i> ATCC ® 27336™
89064	CultiControl™ <i>Streptococcus sanguinis</i> ATCC ® 10556™
89065	CultiControl™ <i>Enterobacter cloacae</i> subsp. <i>cloacae</i> ATCC ® BAA-1143™
89066	CultiControl™ <i>Enterococcus faecalis</i> ATCC ® 49532™
89067	CultiControl™ <i>Enterococcus faecalis</i> ATCC ® 49533™
89068	CultiControl™ <i>Escherichia coli</i> NCTC 11954™
89069	CultiControl™ <i>Klebsiella pneumoniae</i> ATCC ® BAA-2146™
89070	CultiControl™ <i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i> ATCC ® 700603™
89071	CultiControl™ <i>Candida parapsilosis</i> ATCC ® 22019™
89072	CultiControl™ <i>Candida albicans</i> ATCC ® 90028™
89073	CultiControl™ <i>Issatchenkia orientalis</i> ATCC ® 6258™
89074	CultiControl™ <i>Neisseria gonorrhoeae</i> ATCC ® 19424™
89075	CultiControl™ <i>Neisseria gonorrhoeae</i> ATCC ® 31426™
89076	CultiControl™ <i>Haemophilus influenzae</i> ATCC® 49766™
89077	CultiControl™ <i>Haemophilus influenzae</i> ATCC® 49247™
89078	CultiControl™ <i>Bacteroides fragilis</i> ATCC® 25285™
89079	CultiControl™ <i>Bacteroides thetaiotaomicron</i> ATCC® 29741™
89080	CultiControl™ <i>Lactobacillus acidophilus</i> ATCC ® 4356™
89081	CultiControl™ <i>Lactobacillus leichmannii</i> ATCC ® 4797™
89082	CultiControl™ <i>Lactococcus lactis</i> ATCC ® 19435™
89083	CultiControl™ <i>Proteus mirabilis</i> ATCC ® 29906™
89084	CultiControl™ <i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Enteritidis</i> ATCC ® 13076™
89085	CultiControl™ <i>Listeria monocytogenes</i> ATCC ® 13932™
89086	CultiControl™ <i>Campylobacter jejuni</i> ATCC ® 33291™
89087	CultiControl™ <i>Klebsiella pneumoniae</i> ATCC ® BAA-1706™

89088	CultiControl™ <i>Klebsiella pneumoniae</i> ATCC ® BAA-1705™
89089	CultiControl™ <i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i> ATCC ® 13883™
89090	CultiControl™ <i>Clostridium difficile</i> ATCC ® 9689™
89091	CultiControl™ <i>Aggregatibacter aphrophilus</i> ATCC ® 7901™
89092	CultiControl™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC® 700698™
89093	CultiControl™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC ® 700699™
89094	CultiControl™ <i>Plesiomonas shigelloides</i> ATCC ® 14029™
89095	CultiControl™ <i>Clostridium sporogenes</i> ATCC ® 19404™
89096	CultiControl™ <i>Micrococcus luteus</i> ATCC ® 10240™
89097	CultiControl™ <i>Candida tropicalis</i> ATCC ® 750™
89098	CultiControl™ <i>Candida krusei</i> ATCC ® 14243™
89099	CultiControl™ <i>Gardnerella vaginalis</i> ATCC ® 14018™
89100	CultiControl™ <i>Lactobacillus fermentum</i> ATCC ® 9338™
89101	CultiControl™ <i>Listeria grayi</i> ATCC ® 25401™
89102	CultiControl™ <i>Micrococcus luteus</i> ATCC ® 4698™
89103	CultiControl™ <i>Moraxella (Branhamella) catarrhalis</i> ATCC ® 25238™
89104	CultiControl™ <i>Neisseria gonorrhoeae</i> ATCC ® 49226™
89105	CultiControl™ <i>Proteus mirabilis</i> ATCC ® 35659™
89106	CultiControl™ <i>Proteus mirabilis</i> ATCC ® 43071™
89107	CultiControl™ <i>Proteus vulgaris</i> ATCC ® 6380™
89108	CultiControl™ <i>Pseudomonas aeruginosa</i> ATCC ® 10145™
89109	CultiControl™ <i>Pseudomonas aeruginosa</i> ATCC ® 15442™
89110	CultiControl™ <i>Pseudomonas fluorescens</i> ATCC ® 13525™
89111	CultiControl™ <i>Bacteroides ovatus</i> ATCC ® 8483™
89112	CultiControl™ <i>Clostridium histolyticum</i> ATCC ® 19401™
89113	CultiControl™ <i>Bacteroides fragilis</i> ATCC ® 23745™
89114	CultiControl™ <i>Actinomyces odontolyticus</i> ATCC ® 17929™
89115	CultiControl™ <i>Enterococcus faecalis</i> ATCC ® 33186™
89116	CultiControl™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC ® 33591™
89117	CultiControl™ <i>Enterococcus faecium</i> ATCC ® 51559™
89118	CultiControl™ <i>Fusobacterium nucleatum</i> ATCC ® 25586™
89119	CultiControl™ <i>Aeromonas hydrophila</i> ATCC ® 7966™
89120	CultiControl™ <i>Haemophilus influenzae</i> ATCC ® 10211™
89121	CultiControl™ <i>Serratia marcescens</i> ATCC ® 8100™
89122	CultiControl™ <i>Neisseria gonorrhoeae</i> ATCC ® 49981™
89123	CultiControl™ <i>Haemophilus haemolyticus</i> ATCC ® 33390™
89124	CultiControl™ <i>Haemophilus influenzae</i> ATCC ® 33533™
89125	CultiControl™ <i>Providencia stuartii</i> ATCC ® 33672™
89126	CultiControl™ <i>Staphylococcus haemolyticus</i> ATCC ® 29970™
89127	CultiControl™ <i>Streptococcus anginosus</i> ATCC ® 33397™
89128	CultiControl™ <i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i> ATCC ® 12388™
89129	CultiControl™ <i>Streptococcus mitis</i> ATCC ® 6249™
89130	CultiControl™ <i>Streptococcus pyogenes</i> ATCC ® 49399™
89131	CultiControl™ <i>Streptococcus salivarius</i> ATCC® 13419™
89132	CultiControl™ <i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Abony</i> NCTC 6017
89133	CultiControl™ <i>Staphylococcus xylosum</i> ATCC ® 29971™
89135	CultiControl™ <i>Propionibacterium acnes</i> ATCC® 11827™
89136	CultiControl™ <i>Haemophilus influenzae</i> NCTC 8468
89137	CultiControl™ <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC ® 19095™
89138	CultiControl™ <i>Cronobacter sakazakii</i> ATCC ® 29544™
89139	CultiControl™ <i>Bordetella bronchiseptica</i> ATCC ® 4617™
89140	CultiControl™ <i>Trichophyton mentagrophytes</i> ATCC ® 9533™

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89141	CultiControl™ Acinetobacter baumannii ATCC ® BAA-747™
89144	CultiControl™ Vibrio alginolyticus ATCC ® 17749™
89145	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 33560™
89146	CultiControl™ Citrobacter freundii ATCC ® 43864™
89147	CultiControl™ Burkholderia cepacia ATCC ® 25416™
89148	CultiControl™ Listeria monocytogenes ATCC ® 35152™
89149	CultiControl™ Stenotrophomonas maltophilia ATCC® 13637™
89151	CultiControl™ Legionella pneumophila subsp. fraseri ATCC ® 33156™
89152	CultiControl™ Enterococcus faecium ATCC ® 6057™
89154	CultiControl™ Salmonella enterica subsp. arizonae ATCC ® 13314™
89156	CultiControl™ Enterobacter aerogenes ATCC ® 13048™
89160	CultiControl™ Haemophilus influenzae ATCC ® 19418™
89163	CultiControl™ Escherichia coli ATCC ® 35218™
89164	CultiControl™ Neisseria meningitidis ATCC ® 13090™
89165	CultiControl™ Peptostreptococcus anaerobius ATCC ® 27337™
89170	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® BAA-44™
89171	CultiControl™ Enterococcus faecium ATCC ® 19434™
89172	CultiControl™ Enterococcus faecium ATCC ® BAA-2319™
89173	CultiControl™ Enterococcus faecalis ATCC ® 51299™
89174	CultiControl™ Acinetobacter baumannii ATCC ® 19606™
89175	CultiControl™ Streptococcus pneumoniae ATCC ® 700671™
89176	CultiControl™ Haemophilus influenzae ATCC ® 33391™
89177	CultiControl™ Candida albicans ATCC ® 18804™
89178	CultiControl™ Candida albicans ATCC ® 64124™
9001	NALIDIXIC ACID NA 30 µg 250 Discs
9001/1	NALIDIXIC ACID NA 30 µg 50 Discs
9002	Oxolinic acid OA 2 µg 250 Discs
9002/1	Oxolinic acid OA 2 µg 50 Discs
9003	PIPEMIDIC ACID PI 20 µg 250 Discs
9003/1	PIPEMIDIC ACID PI 20 µg 50 Discs
9004	AMIKACIN AK 30 µg 250 Discs
9004/1	AMIKACIN AK 30 µg 50 Discs
9005	AMOXICILLIN AML 30 µg 250 Discs
9005/1	AMOXICILLIN AML 30 µg 50 Discs
9006	AMPICILLIN AMP 10 µg 250 Discs
9006/1	AMPICILLIN AMP 10 µg 50 Discs
9007	AZLOCILLIN AZL 75 µg 250 Discs
9007/1	AZLOCILLIN AZL 75 µg 50 Discs
9008	AZTREONAM ATM 30 µg 250 Discs
9008/1	AZTREONAM ATM 30 µg 50 Discs
9009	CARBENICILLIN CAR 100 µg 250 Discs
9009/1	CARBENICILLIN CAR 100 µg 50 Discs
9010	CEFACLOR CEC 30 µg 250 Discs
9010/1	CEFACLOR CEC 30 µg 50 Discs
9011	CEPHALEXIN CL 30 µg 250 Discs
9011/1	CEPHALEXIN CL 30 µg 50 Discs
9013	CEPHALOTHIN KF 30 µg 250 Discs
9013/1	CEPHALOTHIN KF 30 µg 50 Discs
9014	CEFAMANDOLE MA 30 µg 250 Discs
9014/1	CEFAMANDOLE MA 30 µg 50 Discs
9015	CEFAZOLIN KZ 30 µg 250 Discs
9015/1	CEFAZOLIN KZ 30 µg 50 Discs
9016	CEFOPERAZONE CFP 30 µg 250 Discs
9016/1	CEFOPERAZONE CFP 30 µg 50 Discs
9017	CEFOTAXIME CTX 30 µg 250 Discs
9017/1	CEFOTAXIME CTX 30 µg 50 Discs
9018	CEFOXITIN FOX 30 µg 250 Discs

9018/1	CEFOXITIN FOX 30 µg 50 Discs
9019	CEFTAZIDIME CAZ 30 µg 250 Discs
9019/1	CEFTAZIDIME CAZ 30 µg 50 Discs
9020	CEFTRIAZONE CRO 30 µg 250 Discs
9020/1	CEFTRIAZONE CRO 30 µg 50 Discs
9021	CEFUROXIME CXM 30 µg 250 Discs
9021/1	CEFUROXIME CXM 30 µg 50 Discs
9022	CHLORAMPHENICOL C 30 µg 250 Discs
9022/1	CHLORAMPHENICOL C 30 µg 50 Discs
9023	COLISTIN SULFATE CS 10 µg 250 Discs
9023/1	COLISTIN SULFATE CS 10 µg 50 Discs
9024	ERYTHROMYCIN E 15 µg 250 Discs
9024/1	ERYTHROMYCIN E 15 µg 50 Discs
9025	FOSFOMYCIN FOS 50 µg 250 Discs
9025/1	FOSFOMYCIN FOS 50 µg 50 Discs
9026	GENTAMICIN CN 10 µg 250 Discs
9026/1	GENTAMICIN CN 10 µg 50 Discs
9027	KANAMYCIN K 30 µg 250 Discs
9027/1	KANAMYCIN K 30 µg 50 Discs
9028	LINCOMYCIN MY 2 µg 250 Discs
9028/1	LINCOMYCIN MY 2 µg 50 Discs
9029	METHICILLIN MET 5 µg 250 Discs
9029/1	METHICILLIN MET 5 µg 50 Discs
9030	MINOCYCLINE MN 30 µg 250 Discs
9030/1	MINOCYCLINE MN 30 µg 50 Discs
9031	AMPICILLIN-SULBACTAM AMS 20 µg 250 Discs
9031/1	AMPICILLIN-SULBACTAM AMS 20µg 50 DISCS
9032	NEOMYCIN N 30 µg 250 Discs
9032/1	NEOMYCIN N 30 µg 50 Discs
9033	NETILMICIN NET 30 µg 250 Discs
9033/1	NETILMICIN NET 30 µg 50 Discs
9034	NITROFURANTOIN F 300 µg 250 Discs
9034/1	NITROFURANTOIN F 300 µg 50 Discs
9035	NORFLOXACIN NOR 10µg 250 Discs
9035/1	NORFLOXACIN NOR 10 µg 50 Discs
9036	OXACILLIN OX 1µg 250 Discs
9036/1	OXACILLIN OX 1 µg 50 Discs
9037	PENICILLIN G P 10 IU 250 Discs
9037/1	PENICILLIN G P 10 IU 50 Discs
9038	PIPERACILLIN PRL 100 µg 250 Discs
9038/1	PIPERACILLIN PRL 100 µg 50 Discs
9039	RIFAMPICIN RD 30 µg 250 Discs
9039/1	RIFAMPICIN RD 30 µg 50 Discs
9040	STREPTOMYCIN S 10 µg 250 Discs
9040/1	STREPTOMYCIN S 10 µg 50 Discs
9041	SULFAMURAZOLE SF 300 µg 250 Discs
9041/1	SULFAMURAZOLE SF 300 µg 50 Discs
9042	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 250 Discs
9042/1	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 50 Discs
9043	TETRACYCLINE TE 30 µg 250 Discs
9043/1	TETRACYCLINE TE 30 µg 50 Discs
9044	TOBRAMYCIN TOB 10 µg 250 Discs
9044/1	TOBRAMYCIN TOB 10 µg 50 Discs
9045	VANCOMYCIN VA 30 µg 250 Discs
9045/1	VANCOMYCIN VA 30 µg 50 Discs
9046	SISOMYCIN SIS 30µg 250 Discs
9046/1	SISOMYCIN SIS 30 µg 50 Discs
9047	CLINDAMYCIN CD 2 µg 250 Discs
9047/1	CLINDAMYCIN CD 2 µg 50 Discs



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9048	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 250 Discs
9048/1	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 50 Discs
9049	FUSIDIC ACID FC 10 µg 250 Discs
9049/1	FUSIDIC ACID FC 10 µg 50 Discs
9050	TEICOPLANIN TEC 30 µg 250 Discs
9050/1	TEICOPLANIN TEC 30 µg 50 Discs
9051	BACITRACIN BA 10 IU 250 Discs
9051/1	BACITRACIN BA 10 IU 50 Discs
9052	CEFADROXIL CDX 30 µg 250 Discs
9052/1	CEFADROXIL CDX 30 µg 50 Discs
9053	CEFSULODIN CSD 30 µg 250 Discs
9053/1	CEFSULODIN CSD 30 µg 50 Discs
9054	CEFTIZOXIME CZX 30 µg 250 Discs
9054/1	CEFTIZOXIME CZX 30 µg 50 Discs
9055	CEPHRADINE CE 30 µg 250 Discs
9055/1	CEPHRADINE CE 30 µg 50 Discs
9056	CIPROFLOXACIN CIP 5 µg 250 Discs
9056/1	CIPROFLOXACIN CIP 5 µg 50 Discs
9057	CINOXACIN CIN 100 µg 250 Discs
9057/1	CINOXACIN CIN 100 µg 50 Discs
9058	CLOXACILLIN CX 5 µg 250 Discs
9058/1	CLOXACILLIN CX 5 µg 50 Discs
9059	DOXYCYCLINE DXT 30 µg 250 Discs
9059/1	DOXYCYCLINE DXT 30 µg 50 Discs
9060	ROXITROMYCIN RXT 15 µg 250 Discs
9060/1	ROXITROMYCIN RXT 15 µg 50 Discs
9061	ERTAPENEM ETP 10 µg 250 Discs
9061/1	ERTAPENEM ETP 10 µg 50 Discs
9062	MEZLOCILLIN MEZ 75 µg 250 Discs
9062/1	MEZLOCILLIN MEZ 75 µg 50 Discs
9063	NOVOBIOCIN NO 30 µg 250 Discs
9063/1	NOVOBIOCIN NO 30 µg 50 Discs
9064	CEFPODOXIME PX 10 µg 250 Discs
9064/1	CEFPODOXIME PX 10 µg 50 Discs
9065	OXYTETRACYCLINE OT 30 µg 250 Discs
9065/1	OXYTETRACYCLINE OT 30 µg 50 Discs
9066	POLYMYXIN B PB 100 IU 250 Discs
9066/1	POLYMYXIN B PB 100 IU 50 Discs
9067	SPECTINOMYCIN SPC 100 µg 250 Discs
9067/1	SPECTINOMYCIN SPC 100 µg 50 Discs
9068	MEROPENEM MRP 10 µg 250 Discs
9068/1	MEROPENEM MRP 10 µg 50 Discs
9069	FLUCONAZOLE FLU 100 µg 250 Discs
9069/1	FLUCONAZOLE FLU 100 µg 50 Discs
9070	TICARCILLIN TC 75 µg 250 Discs
9070/1	TICARCILLIN TC 75 µg 50 Discs
9071	AMPHOTERICIN B AMB 20 µg 250 Discs
9071/1	AMPHOTERICIN B AMB 20 µg 50 Discs
9072	ECONAZOLE ECN 10 µg 250 Discs
9072/1	ECONAZOLE ECN 10 µg 50 Discs
9073	FLUCYTOSINE AFY 1 µg 250 Discs
9073/1	FLUCYTOSINE AFY 1 µg 50 Discs
9074	GRISEOFULVIN AGF 10 µg 250 Discs
9074/1	GRISEOFULVIN AGF 10 µg 50 Discs
9075	KETOCONAZOLE KCA 10 µg 250 Discs
9075/1	KETOCONAZOLE KCA 10 µg 50 Discs
9076	METRONIDAZOLE MTZ 5 µg 250 Discs
9076/1	METRONIDAZOLE MTZ 5 µg 50 Discs
9077	MICONAZOLE MCL 10 µg 250 Discs
9077/1	MICONAZOLE MCL 10 µg 50 Discs

9078	NYSTATIN NY 100 IU 250 Discs
9078/1	NYSTATIN NY 100 IU 50 Discs
9079	IMIPENEM IMI 10 µg 250 Discs
9079/1	IMIPENEM IMI 10 µg 50 Discs
9080	OFLOXACIN OFX 5 µg 250 Discs
9080/1	OFLOXACIN OFX 5 µg 50 Discs
9081	CEFOTETAN CTT 30 µg 250 Discs
9081/1	CEFOTETAN CTT 30 µg 50 Discs
9082	TYLOSIN TY 30 µg 250 Discs
9082/1	TYLOSIN TY 30 µg 50 Discs
9083	TRIMETHOPRIM TM 2.5 µg 250 Discs
9083/1	TRIMETHOPRIM TM 2.5 µg 50 Discs
9084	SULFAMETHOXAZOLE SMX 50 µg 250 Discs
9084/1	SULFAMETHOXAZOLE SMX 50 µg 50 Discs
9085	Imipenem + Phenylboronic acid IMI + BO 250 Discs
9085/1	Imipenem + Phenylboronic acid IMI + BO 50 Discs
9086	Imipenem + Cloxacillin IMI + CL 250 Discs
9086/1	Imipenem + Cloxacillin IMI + CL 50 Discs
9087	EDTA ED 250 Discs
9087/1	EDTA ED 50 Discs
9088	SPIRAMYCIN SP 100 µg 250 Discs
9088/1	SPIRAMYCIN SP 100 µg 50 Discs
9089	CEFIXIME CFM 5 µg 250 Discs
9089/1	CEFIXIME CFM 5 µg 50 Discs
9090	Daptomycin DAP 30 µg 250 Discs
9090/1	Daptomycin DAP 30 µg 50 Discs
9091	PEFLOXACIN PEF 5 µg 250 Discs
9091/1	PEFLOXACIN PEF 5 µg 50 Discs
9093	DICLOXACILLIN DCX 1 µg 250 Discs
9093/1	DICLOXACILLIN DCX 1 µg 50 Discs
9094	TIAMULIN T 30 µg 250 Discs
9094/1	TIAMULIN T 30 µg 50 Discs
9095	IMIPENEM/CILASTATIN IMC 20 µg 250 Discs
9095/1	IMIPENEM/CILASTATIN IMC 20 µg 50 Discs
9096	TICARCILLIN-CLAVULINIC ACID TTC 85 µg 250 Discs
9096/1	TICARCILLIN-CLAVULINIC ACID TTC 85 µg 50 Discs
9097	CLOTRIMAZOLE CLO 50 µg 250 Discs
9097/1	CLOTRIMAZOLE CLO 50 µg 50 Discs
9098	CLARITHROMYCIN CLR 15 µg 250 Discs
9098/1	CLARITHROMYCIN CLR 15 µg 50 Discs
9099	FURAZOLIDON FR 50 µg 250 Discs
9099/1	FURAZOLIDON FR 50 µg 50 Discs
9100	PIPERACILLIN-TAZOBACTAM TZP 110 µg 250 Discs
9100/1	PIPERACILLIN-TAZOBACTAM TZP 110 µg 50 Discs
9101	CEFTIBUTEN CTB 30 µg 250 Discs
9101/1	CEFTIBUTEN CTB 30 µg 50 Discs
9102	LEVOFLOXACIN LEV 5 µg 250 Discs
9102/1	LEVOFLOXACIN LEV 5 µg 50 Discs
9103	MOXIFLOXACIN MOX 5 µg 250 Discs
9103/1	MOXIFLOXACIN MOX 5 µg 50 Discs
9104	CEFEPIME FEP 30 µg 250 Discs
9104/1	CEFEPIME FEP 30 µg 50 Discs
9105	AZITHROMYCIN AZM 15 µg 250 Discs
9105/1	AZITHROMYCIN AZM 15 µg 50 Discs
9106	MYOKAMYCIN MK 15 µg 250 Discs
9106/1	MYOKAMYCIN MK 15 µg 50 Discs
9107	ITRACONAZOLE ITC 50 µg 250 Discs
9107/1	ITRACONAZOLE ITC 50 µg 50 Discs
9108	CEFOPERAZONE CFP 75 µg 250 Discs
9108/1	CEFOPERAZONE CFP 75 µg 50 Discs

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9109	FOSFOMYCIN (includes G-6-p) FOS 200 µg 250 Discs
9109/1	FOSFOMYCIN (includes G-6-p) FOS 200 µg 50 Discs
9110	TRIMETHOPRIM TM 5 µg 250 Discs
9110/1	TRIMETHOPRIM TM 5 µg 50 Discs
9111	FUSIDIC ACID FC 30 µg 250 Discs
9111/1	FUSIDIC ACID FC 30 µg 50 Discs
9112	CEFPROZIL CPR 30 µg 250 Discs
9112/1	CEFPROZIL CPR 30 µg 50 Discs
9113	LOMEFLOXACIN LOM 10 µg 250 Discs
9113/1	LOMEFLOXACIN LOM 10 µg 50 Discs
9115	AMPICILLIN AMP 2 µg 250 Discs
9115/1	AMPICILLIN AMP 2 µg 50 Discs
9116	LINCOMYCIN MY 15 µg 250 Discs
9116/1	LINCOMYCIN MY 15 µg 50 Discs
9117	NOVOBIOCIN NO 5 µg 250 Discs
9117/1	NOVOBIOCIN NO 5 µg 50 Discs
9118	RIFAMPICIN RD 5 µg 250 Discs
9118/1	RIFAMPICIN RD 5µg 50 Discs
9119	METRONIDAZOLE MTZ 50 µg 250 Discs
9119/1	METRONIDAZOLE MTZ 50 µg 50 Discs
9120	POLYMYXIN B PB 300 UI 250 Discs
9120/1	POLYMYXIN B PB 300 UI 50 Discs
9121	FOSFOMYCIN (includes G-6-p) FOS 100 µg 250 Discs
9121/1	FOSFOMYCIN (includes G-6-p) FOS 100 µg 50 Discs
9122	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 250 Discs
9122/1	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 50 Discs
9124	GENTAMICIN CN 120 µg 250 Discs
9124/1	GENTAMICIN CN 120 µg 50 Discs
9125	GENTAMICIN CN 30 µg 250 Discs
9125/1	GENTAMICIN CN 30 µg 50 Discs
9126	SULFONAMIDE S3 300 µg 250 Discs
9126/1	SULFONAMIDE S3 300 µg 50 Discs
9127	PENICILLIN G P 2 IU 250 Discs
9127/1	PENICILLIN G P 2 IU 50 Discs
9128	CHLORAMPHENICOL C 10 µg 250 Discs
9128/1	CHLORAMPHENICOL C 10 µg 50 Discs
9129	SULBACTAM SU 20µg 250 Discs
9129/1	SULBACTAM SU 20µg 50 Discs
9130	PENICILLIN G P 1 IU 250 Discs
9130/1	PENICILLIN G P 1 IU 50 Discs
9131	SODIUM FUSIDATE FC 30 250 Discs
9132	SULFAPRIM SXT 50 µg 250 Discs
9132/1	SULFAPRIM SXT 50 µg 50 Discs
9133	AMOXICILLIN AML 10 µg 250 Discs
9133/1	AMOXICILLIN AML 10 µg 50 Discs
9134	CEFOTAXIME CTX 75 µg 250 Discs
9134/1	CEFOTAXIME CTX 75 µg 50 Discs
9135	OXACILLIN OX 5µg 250 Discs
9135/1	OXACILLIN OX 5µg 50 Discs
9136	LINEZOLID LNZ 30µg 250 Discs
9136/1	LINEZOLID LNZ 30µg 50 Discs
9137	AMPHOTERICIN B AMB 10 µg 250 Discs
9137/1	AMPHOTERICIN B AMB 10 µg 50 Discs
9139	ITRACONAZOLE ITC 8 µg 250 Discs
9139/1	ITRACONAZOLE ITC 8 µg 50 Discs
9140	KETOCONAZOLE KCA 15 µg 250 Discs
9140/1	KETOCONAZOLE KCA 15 µg 50 Discs
9141	COLISTIN SULFATE CS 30 UI 250 Discs
9141/1	COLISTIN SULFATE CS 30 UI 50 Discs
9142	STREPTOMYCIN S 300 µg 250 Discs

9142/1	STREPTOMYCIN S 300 µg 50 Discs
9143	CEFEPIME+CLAVULANIC ACID FEL 40 µg 250 Discs
9144	Cefoxitin+Cloxacillin FOC 230 µg 250 Discs
9144/1	Cefoxitin+Cloxacillin FOC 230 µg 50 Discs
9145	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 250 Discs
9145/1	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 50 Discs
9146	CLINDAMYCIN CD 10 µg 250 Discs
9146/1	CLINDAMYCIN CD 10 µg 50 Discs
9147	TIGECYCLIN TGC 15 µg 250 Discs
9147/1	TIGECYCLIN TGC 15 µg 50 Discs
9148	FLUCYTOSINE AFY 10 µg 250 Discs
9148/1	FLUCYTOSINE AFY 10 µg 50 Discs
9150	SULFADIAZINE SUZ 300 ug 250 Discs
9150/1	SULFADIAZINE SUZ 300 ug 50 Discs
9151	AMOXICILLIN AML 2 µg 250 Discs
9151/1	AMOXICILLIN AML 2 µg 50 Discs
9152	CEFOTAXIME CTX 5 µg 250 Discs
9152/1	CEFOTAXIME CTX 5 µg 50 Discs
9153	CEFTAZIDIME CAZ 10 µg 250 Discs
9153/1	CEFTAZIDIME CAZ 10 µg 50 Discs
9154	DORIPENEM DOR 10 µg 250 Discs
9154/1	DORIPENEM DOR 10 µg 50 Discs
9155	LINEZOLID LNZ 10 µg 250 Discs
9155/1	LINEZOLID LNZ 10 µg 50 Discs
9156	MECILLINAM MEC 10 µg 250 Discs
9156/1	MECILLINAM MEC 10 µg 50 Discs
9157	MUPIROCIN MUP 200 µg 250 Discs
9157/1	MUPIROCIN MUP 200 µg 50 Discs
9158	NITROFURANTOIN F 100 µg 250 Discs
9158/1	NITROFURANTOIN F 100 µg 50 Discs
9159	PIPERACILLIN PRL 30 µg 250 Discs
9159/1	PIPERACILLIN PRL 30 µg 50 Discs
9160	PIPERACILLIN-TAZOBACTAM TZP 36 µg 250 Discs
9160/1	PIPERACILLIN-TAZOBACTAM TZP 36 µg 50 Discs
9161	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 250 Discs
9161/1	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 50 Discs
9162	STREPTOMYCIN S 300 µg 250 Discs
9162/1	STREPTOMYCIN S 300 µg 50 Discs
9163	TOBRAMYCIN TOB 30 ug 250 Discs
9163/1	TOBRAMYCIN TOB 30 ug 50 Discs
9164	VANCOMYCIN VA 5 µg 250 Discs
9164/1	VANCOMYCIN VA 5 µg 50 Discs
9165	CASPOFUNGIN CAS 5 µg 250 Discs
9165/1	CASPOFUNGIN CAS 5 µg 50 Discs
9166	FLUCONAZOLE FLU 25 µg 250 Discs
9166/1	FLUCONAZOLE FLU 25 µg 50 Discs
9167	POSACONAZOLE POS 5 µg 250 Discs
9167/1	POSACONAZOLE POS 5 µg 50 Discs
9168	VORICONAZOLE VO 1 µg 250 Discs
9168/1	VORICONAZOLE VO 1 µg 50 Discs
9169	GATIFLOXACIN GAT 5 µg 250 Discs
9169/1	GATIFLOXACIN GAT 5 µg 50 Discs
9170	NETILMICIN NET 10 µg 250 Discs
9170/1	NETILMICIN NET 10 µg 50 Discs
9171	PHENOXYMETHYLPENICILLIN PV 10 µg 250 Discs
9171/1	PHENOXYMETHYLPENICILLIN PV 10 µg 50 Discs
9172	TELITHROMYCIN TEL 15 µg 250 Discs
9172/1	TELITHROMYCIN TEL 15 µg 50 Discs
9173	LORACARBEF LOR 30 µg 250 Discs
9173/1	LORACARBEF LOR 30 µg 50 Discs

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9174	NAFCILLIN NAF 1 µg 250 Discs
9174/1	NAFCILLIN NAF 1 µg 50 Discs
9175	MEROPENEM+CLOXACILLIN MR+CL 250 Discs
9175/1	MEROPENEM+CLOXACILLIN MR+CL 50 Discs
9176	Meropenem + Phenylboronic acid MR + BO 250 Discs
9176/1	Meropenem + Phenylboronic acid MR + BO 50 Discs
9177	MEROPENEM+DIPICOLINIC ACID MR+DP 250 Discs
9177/1	MEROPENEM+DIPICOLINIC ACID MR+DP 50 Discs
9178	Meropenem + EDTA MR + ED 250 Discs
9178/1	Meropenem + EDTA MR + ED 50 Discs
9179	AMOXICILLIN AML 25 µg 250 Discs
9179/1	AMOXICILLIN AML 25 µg 50 Discs
9181	NITROFURANTOIN F 50 µg 250 Discs
9181/1	NITROFURANTOIN F 50 µg 50 Discs
9182	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 250 Discs
9182/1	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 50 Discs
9183	Imipenem + EDTA IMI + ED 250 Discs
9183/1	Imipenem + EDTA IMI + ED 50 Discs
9184	COLISTIN SULFATE CS 25 µg 250 Discs
9184/1	COLISTIN SULFATE CS 25 µg 50 Discs
9185	CEFPIROME CR 30 µg 250 Discs
9185/1	CEFPIROME CR 30 µg 50 Discs
9186	TEMOCILLIN TMO 30 µg 250 Discs
9186/1	TEMOCILLIN TMO 30 µg 50 Discs
9187	Sulfamethoxazole SMX 100 µg 250 Discs
9187/1	Sulfamethoxazole SMX 100 µg 50 Discs
9188	Metronidazole MTZ 10 µg 250 Discs
9188/1	Metronidazole MTZ 10 µg 50 Discs
9189	MUPIROCIN MUP 5 µg 250 Discs
9190	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 250 Discs
9190/1	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 50 Discs
9191	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 250 Discs
9191/1	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 50 Discs
9192	ROKITAMYCIN ROK 30 µg 250 Discs
9192/1	ROKITAMYCIN ROK 30 µg 50 Discs
9193	Phenylboronic acid BO 250 Discs
9193/1	Phenylboronic acid BO 50 Discs
9194	DIPICOLINIC ACID DP 250 Discs
9194/1	DIPICOLINIC ACID DP 50 Discs
9195	CEFTAROLINE CPT 5 µg 250 Discs
9195/1	CEFTAROLINE CPT 5 µg 50 Discs
9198	CEFTAROLINE CPT 30 µg 250 Discs
9198/1	CEFTAROLINE CPT 30 µg 50 Discs
9199	ERTAPENEM+CLOXACILLIN ET+CL 250 Discs
9199/1	ERTAPENEM+CLOXACILLIN ET+CL 50 Discs
9201	ORITAVANCIN ORI 25 µg 250 Discs
9201/1	ORITAVANCIN ORI 25 µg 50 Discs
9202	Ertapenem+Phenylboronic acid ET+BO 250 Discs
9202/1	Ertapenem+Phenylboronic acid ET+BO 50 Discs
9203	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 250 Discs
9203/1	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 50 Discs
9204	Ceftazidime+Clavulanic acid+Cloxacillin CALC 250 Discs
9204/1	Ceftazidime+Clavulanic acid+Cloxacillin CALC 50 Discs
9205	Ceftazime-avibactam CZA 50 µg 250 Discs
9205/1	Ceftazime-avibactam CZA 50 µg 50 Discs
9206	Ceftazime-avibactam CZA 14 µg 250 Discs
9206/1	Ceftazime-avibactam CZA 14 µg 50 Discs
9207	Ulifloxacin ULI 5 µg 250 Discs
9207/1	Ulifloxacin ULI 5 µg 50 Discs

91200	DISC DISPENSER 8 CARTRIDGES
91203	DISC DISPENSER 6 CARTRIDGES
92000	AMOX*/SULB 2/1 AXS 0.016-256* 30 MIC Tests
920000	AMOX*/SULB 2/1 AXS 0.016-256* 100 MIC Tests
92001	RIFAMPICIN RD 0.002-32 30 MIC Tests
920010	RIFAMPICIN RD 0.002-32 100 MIC Tests
920011	RIFAMPICIN RD 0.002-32 10 MIC Tests
92002	FUSIDIC ACID FU 0.016-256 30 MIC Tests
920020	FUSIDIC ACID FU 0.016-256 100 MIC Tests
920021	FUSIDIC ACID FU 0.016-256 10 MIC Tests
92003	AMPICILLIN AMP 0.016-256 30 MIC Tests
920030	AMPICILLIN AMP 0.016-256 100 MIC Tests
920031	AMPICILLIN AMP 0.016-256 10 MIC Tests
92004	POLYMYXIN B PB 0.064-1024 30 MIC Tests
920040	POLYMYXIN B PB 0.064-1024 100 MIC Tests
920041	POLYMYXIN B PB 0.064-1024 10 MIC Tests
92005	CEFPODOXIME PX 0.016-256 30 MIC Tests
920050	CEFPODOXIME PX 0.016-256 100 MIC Tests
920051	CEFPODOXIME PX 0.016-256 10 MIC Tests
92006	CEFOTAXIME CTX 0.016-256 30 MIC Tests
920060	CEFOTAXIME CTX 0.016-256 100 MIC Tests
920061	CEFOTAXIME CTX 0.016-256 10 MIC Tests
92007	CEFOTAXIME CTX 0.002-32 30 MIC Tests
920070	CEFOTAXIME CTX 0.002-32 100 MIC Tests
920071	CEFOTAXIME CTX 0.002-32 10 MIC Tests
92008	CEFPIROME CR 0.016-256 30 MIC Tests
920080	CEFPIROME CR 0.016-256 100 MIC Tests
920081	CEFPIROME CR 0.016-256 10 MIC Tests
92009	GENTAMICIN CN 0.016-256 30 MIC Tests
920090	GENTAMICIN CN 0.016-256 100 MIC Tests
920091	GENTAMICIN CN 0.016-256 10 MIC Tests
92010	GENTAMICIN CN 0.064-1024 30 MIC Tests
920100	GENTAMICIN CN 0.064-1024 100 MIC Tests
920101	GENTAMICIN CN 0.064-1024 10 MIC Tests
92011	GATIFLOXACIN GAT 0.002-32 30 MIC Tests
920110	GATIFLOXACIN GAT 0.002-32 100 MIC Tests
920111	GATIFLOXACIN GAT 0.002-32 10 MIC Tests
92012	TEICOPLANIN TEC 0.016-256 30 MIC Tests
920120	TEICOPLANIN TEC 0.016-256 100 MIC Tests
920121	TEICOPLANIN TEC 0.016-256 10 MIC Tests
92013	ENROFLOXACIN ENR 0.002-32 30 MIC Tests
920130	ENROFLOXACIN ENR 0.002-32 100 MIC Tests
920131	ENROFLOXACIN ENR 0.002-32 10 MIC Tests
92014	SPECTINOMYCIN SPC 0.064-1024 30 MIC Tests
920140	SPECTINOMYCIN SPC 0.064-1024 100 MIC Tests
920141	SPECTINOMYCIN SPC 0.064-1024 10 MIC Tests
92015	OXACILLIN OX 0.016-256 30 MIC Tests
920150	OXACILLIN OX 0.016-256 100 MIC Tests
920151	OXACILLIN OX 0.016-256 10 MIC Tests
92016	CEFTIZOXIME CZX 0.016-256 30 MIC Tests
920160	CEFTIZOXIME CZX 0.016-256 100 MIC Tests
920161	CEFTIZOXIME CZX 0.016-256 10 MIC Tests
92017	MECILLINAM MEC 0.002-32 30 MIC Tests
920170	MECILLINAM MEC 0.002-32 100 MIC Tests
920171	MECILLINAM MEC 0.002-32 10 MIC Tests
92018	AMIKACIN AK 0.016-256 30 MIC Tests
920180	AMIKACIN AK 0.016-256 100 MIC Tests
920181	AMIKACIN AK 0.016-256 10 MIC Tests
92019	BACITRACIN BA 0.016-256 30 MIC Tests
920190	BACITRACIN BA 0.016-256 100 MIC Tests

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920191	BACITRACIN BA 0.016-256 10 MIC Tests
92020	CEFOTETAN CTT 0.016-256 30 MIC Tests
920200	CEFOTETAN CTT 0.016-256 100 MIC Tests
920201	CEFOTETAN CTT 0.016-256 10 MIC Tests
92021	AMOXICILLIN AML 0.016-256 30 Tests
920210	AMOXICILLIN AML 0.016-256 100 MIC Tests
920211	AMOXICILLIN AML 0.016-256 10 MIC Tests
92022	NITROFURANTOIN F 0.032-512 30 MIC Tests
920220	NITROFURANTOIN F 0.032-512 100 MIC Tests
920221	NITROFURANTOIN F 0.032-512 10 MIC Tests
92023	CEFOB*/SULB 2/1 CPS 0.016-256* 30 MIC Tests
920230	CEFOB*/SULB 2/1 CPS 0.016-256* 100 MIC Tests
920231	CEFOB*/SULB 2/1 CPS 0.016-256* 10 MIC Tests
92024	AMOX*/CLAV 2/1 AMG 0.016-256* 30 MIC Tests
920240	AMOX*/CLAV 2/1 AMG 0.016-256* 100 MIC Tests
920241	AMOX*/CLAV 2/1 AMG 0.016-256* 10 MIC Tests
92025	RIFAMPICIN RD 0.016-256 30 MIC Tests
920250	RIFAMPICIN RD 0.016-256 100 MIC Tests
920251	RIFAMPICIN RD 0.016-256 10 MIC Tests
92026	QUIN-DALFOPRIST QDA 0.002-32 30 MIC Tests
920260	QUIN-DALFOPRIST QDA 0.002-32 100 MIC Tests
920261	QUIN-DALFOPRIST QDA 0.002-32 10 MIC Tests
92027	AMPIC*/SULB 2/1 AMS 0.016-256* 30 MIC Tests
920270	AMPIC*/SULB 2/1 AMS 0.016-256* 100 MIC Tests
920271	AMPIC*/SULB 2/1 AMS 0.016-256* 10 MIC Tests
92028	SULBACTAM SUL 0.016-256 30 MIC Tests
920280	SULBACTAM SUL 0.016-256 100 MIC Tests
920281	SULBACTAM SUL 0.016-256 10 MIC Tests
92029	TEMOCILLIN TMO 0.064-1024 30 MIC Tests
920290	TEMOCILLIN TMO 0.064-1024 100 MIC Tests
920291	TEMOCILLIN TMO 0.064-1024 10 MIC Tests
92030	AZITHROMYCIN AZM 0.016-256 30 MIC Tests
920300	AZITHROMYCIN AZM 0.016-256 100 MIC Tests
920301	AZITHROMYCIN AZM 0.016-256 10 MIC Tests
92031	SULFAMETOXAZOLE SMX 0.064-1024 30 MIC Tests
920310	SULFAMETOXAZOLE SMX 0.064-1024 100 MIC Tests
920311	SULFAMETOXAZOLE SMX 0.064-1024 10 MIC Tests
92032	MINOCYCLINE MN 0.016-256 30 MIC Tests
920320	MINOCYCLINE MN 0.016-256 100 MIC Tests
920321	MINOCYCLINE MN 0.016-256 10 MIC Tests
92033	AZTREONAM ATM 0.016-256 30 MIC Tests
920330	AZTREONAM ATM 0.016-256 100 MIC Tests
920331	AZTREONAM ATM 0.016-256 10 MIC Tests
92034	KANAMYCIN K 0.016-256 30 MIC Tests
920340	KANAMYCIN K 0.016-256 100 MIC Tests
920341	KANAMYCIN K 0.016-256 10 MIC Tests
92035	GEMIFLOXACIN GEM 0.002-32 30 MIC Tests
920350	GEMIFLOXACIN GEM 0.002-32 100 MIC Tests
920351	GEMIFLOXACIN GEM 0.002-32 10 MIC Tests
92036	CEFACLOR CEC 0,016-256 30 MIC Tests
920360	CEFACLOR CEC 0,016-256 100 MIC Tests
920361	CEFACLOR CEC 0,016-256 10 MIC Tests
92037	TRIMETHOPRIM TM 0.002-32 30 MIC Tests
920370	TRIMETHOPRIM TM 0.002-32 100 MIC Tests
920371	TRIMETHOPRIM TM 0.002-32 10 MIC Tests
92038	MUPIROCIN MUP 0.064-1024 30 MIC Tests
920380	MUPIROCIN MUP 0.064-1024 100 MIC Tests
920381	MUPIROCIN MUP 0.064-1024 10 MIC Tests
92039	CEPHALOTHIN KF 0.016-256 30 MIC Tests
920390	CEPHALOTHIN KF 0.016-256 100 MIC Tests

920391	CEPHALOTHIN KF 0.016-256 10 MIC Tests
92040	DORIPENEM DOR 0.002-32 30 MIC Tests
920400	DORIPENEM DOR 0.002-32 100 MIC Tests
920401	DORIPENEM DOR 0.002-32 10 MIC Tests
92041	Pefloxacin PEF 0.016-256 mg/L 30 MIC Tests
920410	Pefloxacin PEF 0.016-256 mg/L 100 MIC Tests
920411	Pefloxacin PEF 0.016-256 mg/L 10 MIC Tests
92042	CEFTRIAZONE CRO 0.016-256 30 MIC Tests
920420	CEFTRIAZONE CRO 0.016-256 100 MIC Tests
920421	CEFTRIAZONE CRO 0.016-256 10 MIC Tests
92043	CEFTRIAZONE CRO 0.002-32 30 MIC Tests
920430	CEFTRIAZONE CRO 0.002-32 100 MIC Tests
920431	CEFTRIAZONE CRO 0.002-32 10 MIC Tests
92044	CLOXACILLIN CX 0.016-256 30 MIC Tests
920440	CLOXACILLIN CX 0.016-256 100 MIC Tests
920441	CLOXACILLIN CX 0.016-256 10 MIC Tests
92045	CIPROFLOXACIN CIP 0.002-32 30 MIC Tests
920450	CIPROFLOXACIN CIP 0.002-32 100 MIC Tests
920451	CIPROFLOXACIN CIP 0.002-32 10 MIC Tests
92046	SPIRAMYCIN SP 0.002-32 30 MIC Tests
920460	SPIRAMYCIN SP 0.002-32 100 MIC Tests
920461	SPIRAMYCIN SP 0.002-32 10 MIC Tests
92048	CLARITHROMYCIN CLR 0.016-256 30 MIC Tests
920480	CLARITHROMYCIN CLR 0.016-256 100 MIC Tests
920481	CLARITHROMYCIN CLR 0.016-256 10 MIC Tests
92049	CEFTAROLINE CPT 0.016-256 30 MIC Test
920490	CEFTAROLINE CPT 0.016-256 100 MIC Test
920491	CEFTAROLINE CPT 0.016-256 10 MIC Test
92050	FOSMIDOMYCIN FOM 0.016-256 30 MIC Tests
920500	FOSMIDOMYCIN FOM 0.016-256 100 MIC Tests
920501	FOSMIDOMYCIN FOM 0.016-256 10 MIC Tests
92051	ERYTHROMYCIN E 0.016-256 30 MIC Tests
920510	ERYTHROMYCIN E 0.016-256 100 MIC Tests
920511	ERYTHROMYCIN E 0.016-256 10 MIC Tests
92052	TELAVANCIN TLV 0.002-32 30 MIC Tests
920520	TELAVANCIN TLV 0.002-32 100 MIC Tests
920521	TELAVANCIN TLV 0.002-32 10 MIC Tests
92053	TELAVANCIN TLV 0.016-256 30 MIC Tests
920530	TELAVANCIN TLV 0.016-256 100 MIC Tests
920531	TELAVANCIN TLV 0.016-256 10 MIC Tests
92054	IMIPENEM IMI 0.002-32 30 MIC Tests
920540	IMIPENEM IMI 0.002-32 100 MIC Tests
920541	IMIPENEM IMI 0.002-32 10 MIC Tests
92056	Ceftaroline CPT 0.002-32 30 MIC Tests
920560	Ceftaroline CPT 0.002-32 100 MIC Tests
920561	Ceftaroline CPT 0.002-32 10 MIC Tests
92057	VANCOMYCIN VA 0.016-256 30 MIC Tests
920570	VANCOMYCIN VA 0.016-256 100 MIC Tests
920571	VANCOMYCIN VA 0.016-256 10 MIC Tests
92058	CEFTIBUTEN CTB 0.002-32 30 MIC Tests
920580	CEFTIBUTEN CTB 0.002-32 100 MIC Tests
920581	CEFTIBUTEN CTB 0.002-32 10 MIC Tests
92060	CEFIXIME CFM 0,016-256 30 MIC Tests
920600	CEFIXIME CFM 0,016-256 100 MIC Tests
920601	CEFIXIME CFM 0,016-256 10 MIC Tests
92066	CEFOXITIN FOX 0.016-256 30 MIC Tests
920660	CEFOXITIN FOX 0.016-256 100 MIC Tests
920661	CEFOXITIN FOX 0.016-256 10 MIC Tests
92072	CLINDAMYCIN CD 0.016-256 30 MIC Tests
920720	CLINDAMYCIN CD 0.016-256 100 MIC Tests

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920721	CLINDAMYCIN CD 0,016-256 10 MIC Tests
92075	CHLORAMPHENICOL C 0,016-256 30 MIC Tests
920750	CHLORAMPHENICOL C 0,016-256 100 MIC Tests
920751	CHLORAMPHENICOL C 0,016-256 10 MIC Tests
92078	FOSFOMYCIN FOS 0,016-256 30 MIC Tests
920780	FOSFOMYCIN FOS 0,016-256 100 MIC Tests
920781	FOSFOMYCIN FOS 0,016-256 10 MIC Tests
92079	FOSFOMYCIN FOS 0,064-1024 30 MIC Tests
920790	FOSFOMYCIN FOS 0,064-1024 100 MIC Tests
920791	FOSFOMYCIN FOS 0,064-1024 10 MIC Tests
92081	LEVOFLOXACIN LEV 0.002-32 30 MIC Tests
920810	LEVOFLOXACIN LEV 0.002-32 100 MIC Tests
920811	LEVOFLOXACIN LEV 0.002-32 10 MIC Tests
92084	MEROPENEM MRP 0.002-32 30 MIC Tests
920840	MEROPENEM MRP 0.002-32 100 MIC Tests
920841	MEROPENEM MRP 0.002-32 10 MIC Tests
92087	METRONIDAZOLE MTZ 0.016-256 30 MIC Tests
920870	METRONIDAZOLE MTZ 0.016-256 100 MIC Tests
920871	METRONIDAZOLE MTZ 0.016-256 10 MIC Tests
92090	MOXIFLOXACIN MXF 0,002-32 30 MIC Tests
920900	MOXIFLOXACIN MXF 0,002-32 100 MIC Tests
920901	MOXIFLOXACIN MXF 0,002-32 10 MIC Tests
92093	NETILMICIN NET 0.016-256 30 MIC Tests
920930	NETILMICIN NET 0.016-256 100 MIC Tests
920931	NETILMICIN NET 0.016-256 10 MIC Tests
92096	NORFLOXACIN NOR 0.016-256 30 MIC Tests
920960	NORFLOXACIN NOR 0.016-256 100 MIC Tests
920961	NORFLOXACIN NOR 0.016-256 10 MIC Tests
92099	OFLOXACIN OFX 0.002-32 30 MIC Tests
920990	OFLOXACIN OFX 0.002-32 100 MIC Tests
920991	OFLOXACIN OFX 0.002-32 10 MIC Tests
92102	PENICILLIN G P 0.016-256 30 MIC Tests
921020	PENICILLIN G P 0.016-256 100 MIC Tests
921021	PENICILLIN G P 0.016-256 10 MIC Tests
92103	PENICILLIN G P 0.002-32 30 MIC Tests
921030	PENICILLIN G P 0.002-32 100 MIC Tests
921031	PENICILLIN G P 0.002-32 10 MIC Tests
92105	PIPERACILLIN PIP 0.016-256 30 MIC Tests
921050	PIPERACILLIN PIP 0.016-256 100 MIC Tests
921051	PIPERACILLIN PIP 0.016-256 10 MIC Tests
92108	PIPERAC*/TAZOB TZP 0.016-256* 30 MIC Tests
921080	PIPERAC*/TAZOB TZP 0.016-256* 100 MIC Tests
921081	PIPERAC*/TAZOB TZP 0.016-256* 10 MIC Tests
92111	STREPTOMYCIN S 0.064-1024 30 Tests
921110	STREPTOMYCIN S 0.064-1024 100 MIC Tests
921111	STREPTOMYCIN S 0.064-1024 10 MIC Tests
92112	Streptomycin S 0.016-256 mg/L 30 Tests
921120	Streptomycin S 0.016-256 mg/L 100 MIC Tests
921121	Streptomycin S 0.016-256 mg/L 10 MIC Tests
92114	TETRACYCLINE TE 0.016-25 30 MIC Tests
921140	TETRACYCLINE TE 0.016-25 100 MIC Tests
921141	TETRACYCLINE TE 0.016-25 10 MIC Tests
92117	TICARC*/CLAV TTC 0,016-256* 30MICTests
921170	TICARC*/CLAV TTC 0,016-256* 100 MIC Test
921171	TICARC*/CLAV TTC 0,016-256* 10 MIC Test
92120	TOBRAMYCIN TOB 0,064-1024 30 MIC Tests
921200	TOBRAMYCIN TOB 0,064-1024 100 MIC Tests
921201	TOBRAMYCIN TOB 0,064-1024 10 MIC Tests
92121	TOBRAMYCIN TOB 0,016-256 30 Tests
921210	TOBRAMYCIN TOB 0,016-256 100 Tests

921211	TOBRAMYCIN TOB 0,016-256 10 Tests
92123	TRIM*/SULFAM SXT 0,002-32 30 MIC Tests
921230	TRIM*/SULFAM SXT 0,002-32 100 MIC Tests
921231	TRIM*/SULFAM SXT 0,002-32 10 MIC Tests
92126	CEFEPIME FEP 0.016-256 30 MIC Tests
921260	CEFEPIME FEP 0.016-256 100 MIC Tests
921261	CEFEPIME FEP 0.016-256 10 MIC Tests
92127	CEFEPIME FEP 0.002-32 µg/ml 30 MIC Tests
921270	CEFEPIME FEP 0.002-32 µg/ml 100 MIC Tests
921271	CEFEPIME FEP 0.002-32 µg/ml 10 MIC Tests
92129	CEFUROXIME CXM 0.016-256 30 MIC Tests
921290	CEFUROXIME CXM 0.016-256 100 MIC Tests
921291	CEFUROXIME CXM 0.016-256 10 MIC Tests
92132	NALIDIXIC ACID NA 0,016-256 30 MIC Tests
921320	NALIDIXIC ACID NA 0,016-256 100 MIC Tests
921321	NALIDIXIC ACID NA 0,016-256 10 MIC Tests
92135	LINEZOLID LNZ 0.016-256 30 MIC Tests
921350	LINEZOLID LNZ 0.016-256 100 MIC Tests
921351	LINEZOLID LNZ 0.016-256 10 MIC Tests
92136	TEDIZOLID TZD 0.002-32 30 MIC Tests
921360	TEDIZOLID TZD 0.002-32 100 MIC Tests
921361	TEDIZOLID TZD 0.002-32 10 MIC Tests
92137	Dalbavancin DAL 0.002-32 30 MIC Tests
921370	Dalbavancin DAL 0.002-32 100 MIC Tests
921371	Dalbavancin DAL 0.002-32 10 MIC Tests
92138	CEFTAZIDIME CAZ 0.016-256 30 MIC Tests
921380	CEFTAZIDIME CAZ 0.016-256 100 MIC Tests
921381	CEFTAZIDIME CAZ 0.016-256 10 MIC Tests
92140	Ceftobiprole BPR 0.002-32 mg/L 30 MIC Tests
921400	Ceftobiprole BPR 0.002-32 mg/L 100 MIC Tests
921401	Ceftobiprole BPR 0.002-32 mg/L 10 MIC Tests
92141	COLISTIN CS 0.016-256 30 MIC Tests
921410	COLISTIN CS 0.016-256 100 MIC Tests
921411	COLISTIN CS 0.016-256 10 MIC Tests
92142	COLISTIN CS 0.064-1024 30 MIC Tests
921420	COLISTIN CS 0.064-1024 100 MIC Tests
921421	COLISTIN CS 0.064-1024 10 MIC Tests
92144	TIGECYCLIN TGC 0.016-256 30 MIC Tests
921440	TIGECYCLIN TGC 0.016-256 100 MIC Tests
921441	TIGECYCLIN TGC 0.016-256 10 MIC Tests
92145	DAPTOMYCIN DAP 0.016-256 30 MIC Tests
921450	DAPTOMYCIN DAP 0.016-256 100 MIC Tests
921451	DAPTOMYCIN DAP 0.016-256 10 MIC Tests
92146	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 30 MIC Tests
921460	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 100 MIC Tests
921461	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 10 MIC Tests
92147	FLUCONAZOLE FLU 0.016-256 30 MIC Tests
921470	FLUCONAZOLE FLU 0.016-256 100 MIC Tests
921471	FLUCONAZOLE FLU 0.016-256 10 MIC Tests
92148	ITRACONAZOLE ITC 0.002-32 30 MIC Tests
921480	ITRACONAZOLE ITC 0.002-32 100 MIC Tests
921481	ITRACONAZOLE ITC 0.002-32 10 MIC Tests
92149	FLUCYTOSIN FC 0.002-32 30 MIC Tests
921490	FLUCYTOSIN FC 0.002-32 100 MIC Tests
921491	FLUCYTOSIN FC 0.002-32 10 MIC Tests
92150	VORICONAZOLE VO 0.002-32 30 MIC Tests
921500	VORICONAZOLE VO 0.002-32 100 MIC Tests
921501	VORICONAZOLE VO 0.002-32 10 MIC Tests
92151	KETOCONAZOLE KE 0.002-32 30 MIC Tests

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921510	KETOCONAZOLE KE 0.002-32 100 MIC Tests
921511	KETOCONAZOLE KE 0.002-32 10 MIC Tests
92152	POSACONAZOLE POS 0,002-32 30 MIC Tests
921520	POSACONAZOLE POS 0,002-32 100 MIC Tests
921521	POSACONAZOLE POS 0,002-32 10 MIC Tests
92153	AMPHOTERICIN B AMB 0,002-32 30 MIC Tests
921530	AMPHOTERICIN B AMB 0,002-32 100 MIC Tests
921531	AMPHOTERICIN B AMB 0,002-32 10 MIC Tests
92154	CASPOFUNGIN CAS 0,002-32 30 MIC Tests
921540	CASPOFUNGIN CAS 0,002-32 100 MIC Tests
921541	CASPOFUNGIN CAS 0,002-32 10 MIC Tests
92155	ANIDULAFUNGIN AND 0.002-32 30 MIC Tests
921550	ANIDULAFUNGIN AND 0.002-32 100 MIC Tests
921551	ANIDULAFUNGIN AND 0.002-32 10 MIC Tests
92156	DOXYCYCLINE DXT 0,016-256 30 MIC Tests
921560	DOXYCYCLINE DXT 0,016-256 100 MIC Tests
921561	DOXYCYCLINE DXT 0,016-256 10 MIC Tests
92157	ERTAPENEM ETP 0,002-32 30 MIC Tests
921570	ERTAPENEM ETP 0,002-32 100 MIC Tests
921571	ERTAPENEM ETP 0,002-32 10 MIC Tests
92159	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 30 Tests
921590	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 100 Tests
921591	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 10 Tests
92160	CEFOT./CEFOT.+ CLAV. CTX/CTL 30 MIC Tests
921600	CEFOT./CEFOT.+ CLAV. CTX/CTL 100 MIC Tests
921601	CEFOT./CEFOT.+ CLAV. CTX/CTL 10 MIC Tests
92161	CEFEP./CEFEP.+CLAV. FEP/FEL 30 MIC Tests
921610	CEFEP./CEFEP.+CLAV. FEP/FEL 100 MIC Tests
921611	CEFEP./CEFEP.+CLAV. FEP/FEL 10 MIC Tests
92162	IMIPEN./IMIP.+ EDTA IMI/IMD 30 MIC Tests
921620	IMIPEN./IMIP.+ EDTA IMI/IMD 100 MIC Tests
921621	IMIPEN./IMIP.+ EDTA IMI/IMD 10 MIC Tests
92163	VANCOM/TEICOPLANINA VA/TEC 30 MIC Tests
921630	VANCOM/TEICOPLANINA VA/TEC 100 MIC Tests
921631	VANCOM/TEICOPLANINA VA/TEC 10 MIC Tests
92164	CEFOT/CEFOT+CLOX CTT/CXT0,5-32/0,5-32 30 MIC Tests
921640	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 100 MIC Tests
921641	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 10 MIC Tests
92165	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 30 MIC Tests
921650	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 100 MIC Tests
921651	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 10 MIC Tests
92166	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 30 MIC Tests
921660	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 100 MIC Tests
921661	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 10 MIC Tests
92167	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 30 MIC Tests
921670	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 100 MIC Tests
921671	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 10 MIC Tests
92168	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 30 MIC Tests
921680	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 100 MIC Tests
921681	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 10 MIC Tests
92169	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 30 MIC Tests
921690	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 100 MIC Tests
921691	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 10 MIC Tests

92170	ETHAMBUTOL EB 0.016-256 30 MIC Tests
921700	ETHAMBUTOL EB 0.016-256 100 MIC Tests
921701	ETHAMBUTOL EB 0.016-256 10 MIC Tests
92171	ISONIAZIDE IZ 0.016-256 30 MIC Tests
921710	ISONIAZIDE IZ 0.016-256 100 MIC Tests
921711	ISONIAZIDE IZ 0.016-256 10 MIC Tests
92172	ETHIONAMIDE ET 0.016-256 30 MIC Tests
921720	ETHIONAMIDE ET 0.016-256 100 MIC Tests
921721	ETHIONAMIDE ET 0.016-256 10 MIC Tests
92173	AZTREONAM ATM 0.064-1024 30 MIC Tests
921730	AZTREONAM ATM 0.064-1024 100 MIC Tests
921731	AZTREONAM ATM 0.064-1024 10 MIC Tests
92174	CEFAZOLIN KZ 0.016-256 30 MIC Tests
921740	CEFAZOLIN KZ 0.016-256 100 MIC Tests
921741	CEFAZOLIN KZ 0.016-256 10 MIC Tests
92180	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 30 MIC Tests
921800	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 100 MIC Tests
921801	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 10 MIC Tests
92181	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 30 MIC Tests
921810	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 100 MIC Tests
921811	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 10 MIC Tests
92182	MICAFUNGIN MYC 0,002-32 30 MIC Tests
921820	MICAFUNGIN MYC 0,002-32 100 MIC Tests
921821	MICAFUNGIN MYC 0,002-32 10 MIC Tests
92183	Ticarcillin TC 0.016-256 mg/L 30 MIC Tests
921830	Ticarcillin TC 0.016-256 mg/L 100 MIC Tests
921831	Ticarcillin TC 0.016-256 mg/L 10 MIC Tests
92184	Isavuconazole IVU 0.002-32 mg/L 30 MIC Tests
921840	Isavuconazole IVU 0.002-32 mg/L 100 MIC Tests
921841	Isavuconazole IVU 0.002-32 mg/L 10 MIC Tests
92200	Tiamulin TIA 0.002-32 30 MIC Tests
922000	Tiamulin TIA 0.002-32 100 MIC Tests
922001	Tiamulin TIA 0.002-32 10 MIC Tests
92201	TILMICOSIN TIL 0.002-32 30 MIC Tests
922010	TILMICOSIN TIL 0.002-32 100 MIC Tests
922011	TILMICOSIN TIL 0.002-32 10 MIC Tests
93001	EASY RID h-IgG
93002	EASY RID h-IgA
93003	EASY RID h-IgM
93004	EASY RID h-C3c
93005	EASY RID h-C4
93006	EASY RID h-Transferrin
93007	EASY RID h-Albumin
93008	EASY RID h-Apolipoprotein A1
93009	EASY RID h-Apolipoprotein B
93010	EASY RID h-Alfa 1 Acid Glicoprotein
93011	EASY RID h-Fibrinogen
93012	EASY RID h-Antitrombin III
93013	EASY RID h-Ig Light Chain K
93014	EASY RID h-Ig Light Chain Lambda
93015	Anti h-alfa 1 Antitrypsin
93016	Anti h-Ceruloplasmin
93018	Anti h-Haptoglobin
93104	Multiplate h-IgG/IgA/IgM
93106	MULTIPLATE h-C3c/C4
93110	MULTIPLATE h-Apo A1/Apo B
93115	MULTIPLATE h-Kappa Chain/Lambda Chain
93201	BENCE JONES TEST
940010	RID CONTROL SERUM
9501	OPTOCHINE OPT 100 Discs



# PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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9502	Bacitracin Test 100 Discs
9503	X FACTOR TEST 100 Discs
9504	V FACTOR TEST 100 Discs
9505	V+X FACTOR TEST 100 Discs
9508	METRONIDAZOLE TEST 100 Discs
9511	SULPHONAMIDE TEST 100 Discs
95200	ANAEROBES
95210	ENTEROCOCCI
95220	ENTEROBACTERIA 1
95230	ENTEROBACTERIA URINE
95240	ENTEROBACTERIA 2
95250	PSEUDOMONAS
95260	STAPH
95270	ACINETOBACTER
95280	YEASTS
95290	Strepto
95380	ENTEROBACTERIA
95390	PSEUDOMONAS ACINETOBACTER
95400	ENTEROCOCCI
95410	ANAEROBES
95420	STAPH/STREP
95430	ENTEROBACTERIA URINE
95440	ENTEROBACTERIA FROM URINE AND OTHER SAMPLE
95500	YEASTS
9555	MT-HAEMOPHILUS
9562	URIN-2
9563	MICE
9564	KGL I (Gram + ve) 1 x 100 Test
9565	KGL II (Gram - ve) 1 x 100 Test
9566	KGL III 100 Test
9567	MULTODISC A
9568	MULTODISC B
9569	MULTODISC C
9570	MULTODISC D
9571	MULTODISC A (100 Pz) (Tender106/2003)
9573	MULTODISC C (100 Pz) (Tender106/2003)
9574	MULTODISC D (100 Pz) (Tender106/2003)
9575	URINE RING (Tender238/2006)
9576	PSEUDOMONAS RING (Tender238/2006)
9577	GRAM NEGATIVE RING (Tender238/2006)
9578	GRAM POSITIVE RING (Tender238/2006)
96001	SALMONELLA TYPHI H 20 ml
96002	SALMONELLA TYPHI O 20 ml
96003	SALMONELLA PARATYPHI AH 20 ml
96004	SALMONELLA PARATYPHI AO 20 ml
96005	SALMONELLA PARATYPHI BH 20 ml
96006	SALMONELLA PARATYPHI BO 20 ml
96007	BRUCELLA TOTALE 20 ml
96008	BRUCELLA ABORTUS 20 ml
96009	SALMONELLA TYPHI TOTALE 20 ml CE
96010	SALMONELLA PARATYPHI A TOTALE 20 ml
96011	PROTEUS OX2 20 ml
96012	PROTEUS OXK 20 ml
96013	PROTEUS OX19 20 ml
96015	FEBRILE MULTITEST KIT
96016	STREP-CHECK KIT
96017	STAPH LATEX KIT
96018	SALMONELLA PARATYPHI B TOTALE 20 ml
96019	SALMONELLA PARATYPHI CH 20 ml
96020	SALMONELLA PARATYPHI CO 20 ml

96021	SALMONELLA PARATYPHI C TOTALE 20 ml
96022	BRUCELLA MELITENSIS 20 ml
96023	BRUCELLA SUIIS 20 ml
96031	SALMONELLA TYPHI H SLIDE 5 ml
96032	SALMONELLA TYPHI O SLIDE 5 ml
96033	SALMONELLA TYPHI TOTALE 5 ml SLIDE
96034	SALMONELLA PARATYPHI AH SLIDE 5 ml
96035	SALMONELLA PARATYPHI AO 5 ml SLIDE
96036	SALMONELLA PARATYPHI A TOTALE 5ml SLIDE
96037	SALMONELLA PARATYPHI BH 5 ml SLIDE
96038	SALMONELLA PARATYPHI BO 5 ml SLIDE
96039	SALMONELLA PARATYPHI B TOTALE 5ml SLIDE
96040	SALMONELLA PARATYPHI CH 5 ml SLIDE
96041	SALMONELLA PARATYPHI CO 5 ml SLIDE
96042	SALMONELLA PARATYPHI C TOTALE 5 ml SLIDE
96043	BRUCELLA TOTALE SLIDE 5 ml SLIDE
96044	BRUCELLA ABORTUS 5 ml SLIDE
96045	BRUCELLA MELITENSIS SLIDE 5 ml
96046	BRUCELLA BENGAL ROSE SLIDE 5 ml
96047	PROTEUS OX2 5 ml SLIDE
96048	PROTEUS OX19 5 ml SLIDE
96049	PROTEUS OXK 5 ml SLIDE
96093	CONTROLLO NEGATIVO/NEGATIVE CONTROL 0.5ml
96096	POSITIVE CONTROL FOR SALMONELLA 0.5ml
96097	POSITIVE CONTROL FOR PROTEUS 0.5ml
96098	POSITIVE CONTROL FOR BRUCELLA 0.5ml
96142	Legionella Latex Kit
96143	CAMPYLOBACTER LATEX KIT
96144	CLOSTRIDIUM DIFFICILE LATEX KIT
96148	SHIGELLA ANTISERUM
96150	E. COLI O157 LATEX KIT
96151	SALMONELLA LATEX KIT
96153	STREPTO B LATEX KIT
96154	STREPTO A LATEX KIT
96155	BENCE JONES LATEX TEST
96316	Clostridium difficile GDH Card
96317	Clostridium Difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96321	O157 E.coli Card
96401	ONE STEP AMP DRMG SCREEN 20 CARDS
96404	ONE STEP COC DRMG SCREEN
96405	ONE STEP THC DRMG SCREEN
96406	ONE STEP M-AMP DRMG SCREEN 20 CARDS ONE STEP BRUPRENORPHINE DRMG SCREEN 20 CARDS
96411	FECAL OCCULT BLOOD CARD
96415/20	STREPTO A CARD 30 CARDS
96418	Gonorrhea Ag Card
96441	Gardnerella Vaginalis Card
96442	Trichomonas Vaginalis Card
96443	B.J. Free Kappa/Lambda Dipstick
96444	H.PYLORI CARD 20 CARD
96455	HCG URINE/SERUM CARD 50 CARD
96460	HCG URINE/SERUM CARD 100 CARD
96461	MICROALBUMIN CARD URINE 20 Cards
96462	AFP -ALFA FETO CARD 20 CARDS
96465	TUBERCOLOSI CARD 20 CARDS
96466	IgE TOTAL CARD
96468	CEA CARD 20 Cards

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96487	MYOGLOBIN
96488	TROPONIN 20 CARDS
96490	FERRITIN CARD
96495	SIFILIDE CARD 20 CARDS
96498	IM MONONUCLEOSIS INFECTION 20 CARDS
96590	URINE STRIP
96900	GIOTTO READER
96909	BIOMIC V3
96914	BIOMIC V3 AST
96915	BIOMIC V3 ID
96916	BIOMIC V3 CC
96919	AST Software
96931	ID Software
96932	CC Software
96933	Micropiastre 96 pozzetti Software

97800	ROTASTICK ONE STEP KIT 20 Tests
97801	RSV STICK ONE STEP 20 Tests
97802	ROTA/ADENO COMBI STICK ONE STEP 20 Tests
97803	H.PYLORI FECAL Ag ONE STEP 20 Tests
97805	STREP B STICK ONE STEP ASSAY 20 Tests
97807	ADENOSTICK ONE STEP ASSAY 20 Tests
9999	Blank Discs
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit
99009	AmpC disc kit

Direttore Tecnico/ Technical Director  
Dr.Silvio Brocco



# Declaration of Conformity

helena  
Biosciences Europe

HL-7- 0137 DC DOI 2013/10 (6)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

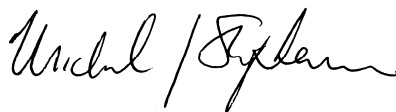
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31<sup>st</sup> October 2013

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United Kingdom

# Declaration of Conformity

helena  
Biosciences Europe

HL-7- 0138 DC DOI 2013/10 (6)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

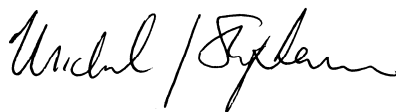
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31<sup>st</sup> October 2013

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# Declaration of Conformity

helena  
Biosciences Europe

HL-7- 0163 DC DOI 2014/05 (8)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5265	Thromboplastin LI	55983
5265H	Thromboplastin LI	55983
5267	Thromboplastin LI	55983
5269	Thromboplastin LI	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 07 May 2014

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United Kingdom

# CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il  
*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da  
*implemented by*

**APTACA S.p.A.**

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di  
*Operative Unit*

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma  
*is in compliance with the standard*

**UNI CEI EN ISO 13485-2016 (ISO 13485-2016)**

per i seguenti Processi  
*concerning the following kinds of Processes*

**Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.**

**Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.**

**Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.**

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.  
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana  
*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

L'AMMINISTRATORE DELEGATO  
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione  
*First Issue Date*  
2007-10-30

Data di Prima Emissione ITALCERT  
*First Issue Date ITALCERT*  
2011-10-30

Data di Rinnovo  
*Renewal Date*  
2020-10-30

Data di Scadenza  
*Expiration Date*  
2023-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*



# CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il  
*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da  
*implemented by*

**APTACA S.p.A.**

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di  
*Operative Unit*

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma  
*is in compliance with the standard*

**UNI EN ISO 9001-2015 (ISO 9001-2015)**

per i seguenti Processi  
*concerning the following kinds of Processes*

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

**Commercializzazione di articoli da laboratorio**

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.  
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana  
*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.*

L'AMMINISTRATORE DELEGATO  
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione  
*First Issue Date*

1998-07-23

Data di Prima Emissione ITALCERT  
*First Issue Date ITALCERT*

2011-10-30

Data di Rinnovo  
*Renewal Date*

2020-10-30

Data di Scadenza  
*Expiration Date*

2023-10-29

Settore IAF 14 - 29



SGQ N° 023A

Membero degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*



# CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il  
*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da  
*implemented by*

**APTACA S.p.A.**

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di  
*Operative Unit*

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma  
*is in compliance with the standard*

**UNI CEI EN ISO 13485-2016 (ISO 13485-2016)**

per i seguenti Processi  
*concerning the following kinds of Processes*

Gestione della fabbricazione e immissione in commercio di tamponi sterili  
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi  
del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in  
Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.  
Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of  
invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile).  
Marketing of medical and diagnostic devices in vitro.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.  
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana  
*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

L'AMMINISTRATORE DELEGATO  
MANAGING DIRECTOR

  
Dr. Ing. Roberto Cusolito

Data di Prima Emissione  
*First Issue Date*  
2007-10-30

Data di Prima Emissione ITALCERT  
*First Issue Date ITALCERT*  
2011-10-30

Data di Rinnovo  
*Renewal Date*  
2020-10-30

Data di Scadenza  
*Expiration Date*  
2023-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

## **DECLARATION OF CONFORMITY**

### **PRODUCT IDENTIFICATION**

<b>Product name</b>	<b>Catalogue number</b>
RPR Carbon kit	044150A 044500A

### **MANUFACTURER**

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

### **MEANS OF CONFORMITY**

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.



Eddy Velthuis  
Technical Director



## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60119814 0001

Report No.: 21265422 001

**Manufacturer:** Macherey-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**Products:** Products for self-testing  
(see attachment for products and sites included)  
Replaces Certificate, Registration No.: HL 60076687 0001

**Expiry Date:** 2022-05-28

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2017-05-29

**Date:** 2017-05-29

Notified Body

  
Dipl.-Ing. Sven Hoffmann



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60119814 0001  
**Report No.:** 21265422 001

**Manufacturer:** Macheray-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**Products for self-testing:**

- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

**Additional site for warehousing and logistics:**

Bahnstr. 120  
52355 Düren, Germany

**Date:** 2017-05-29

**Notified Body**

  
**Dipl.-Ing. Sven Hoffmann**



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

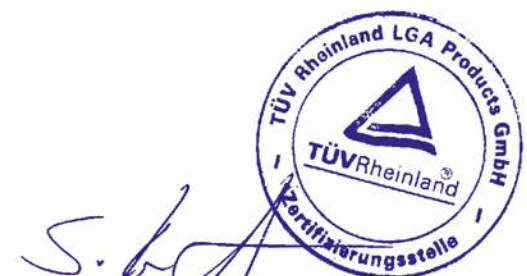
Quality Management System  
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90  
Effective date: 2020-05-29  
Expiry date: 2023-05-28  
Issue date: 2020-05-28



*S. Hoffmann*  
Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



ООО "Медиклон"

127276 Москва, Богатинская ул., 35, т/ф +7495 231-2272 +7499 502-1214

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**АВО, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**( ЦОЛКЛОНЫ Анти-А, Анти-В и Анти-АВ )**  
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

**Наименование:** Цоликлон Анти-А во флаконах по 10 мл с красными крышками

**Серия:** 096111 **Единица:** 100 мл

**Изготовлен:** 05.11.2019 **Количество единиц:** 40

**Годен до:** 05.11.2021 **Объем серии:** 10000 мл

**Паспорт:** А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп A(II) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами групп O(I)	Соответствует Соответствует Соответствует
2.1.1 Ферментагглютинирующая способность	Агглютинация на прозрачности эритроцитов А I и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунда
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на прозрачности эритроцитами группы A(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на прозрачности эритроцитами группы B(III) 1 : 64	Соответствует 1:64 Соответствует 1:32 - 1 : 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009



Заведующая ОТК ООО «Медиклон» М.С. Орлова





МЕДИКТОН

ООО "Медиктон"

127276 Москва, Ботаническая ул., 35, т.ф. +7 495 231-2272 +7 499 502-1214

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**ABO, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**( ЦОЛКЛОНЫ Анти-А, Анти-В и Анти-AB )**  
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

**Наименование:** Цоликлон Анти-В во флаконах по 10 мл с синими крышками

**Серия:** 095810

**Единица:** 100 мл

**Изготовлен:** 21.10.2019

**Количество единиц** 40

**Годен до:** 21.10.2021

**Объем серии:** 10000 мл.

**Паспорт:** B095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная бесцветная жидкость.	
1.3 Цоликлон анти-AB		
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и O(I) Цоликлон анти-AB не должен давать агглютинации с эритроцитами группы O(I) Агглютинация на плоскости эритроцитов А I и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует Соответствует Соответствует Соответствует
2.1.1 Гемагглютинирующая способность	Тип Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1: 64
2.3 Тип	Тип Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64	Соответствует 1:64
	Тип Цоликлона анти-AB в реакции агглютинации на плоскости с эритроцитами групп А(III) 1:32 - 1: 64 и В(III) 1: 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ-9398-101-51203590-2009

Заведующая ОТК ООО «Медиктон»

М.С. Орлова



ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 г. т\ф +7495 231 2272 ф +7499 502 1214

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**ABO, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-AB)**  
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

**Наименование:** Цоликлон Анти-AB  
**Серия:** 098611 **Единица:** 100 мл  
**Изготовлен:** 05.11.2019 **Количество единиц:** 10  
**Годен до:** 05.11.2021 **Объем серии:** 10000 мл.  
**Паспорт:** АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-AB	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и O(I) Цоликлон анти-AB не должен давать агглютинации с эритроцитами группы O(I) Агглютинация на титрности эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует Соответствует Соответствует Соответствует 10 секунд
2.1.1 Фемтаглютинирующая способность	Типр Цоликлона анти-А в реакции агглютинации на титрности с эритроцитами группы А(II) 1:32 - 1:64 Типр Цоликлона анти-В в реакции агглютинации на титрности с эритроцитами группы В(III) 1:32 - 1:64	Соответствует Соответствует 1:32 - 1: 64
2.3 Типр	Типр Цоликлона анти-AB в реакции агглютинации на титрности с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1: 64	Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



**МЕДИКЛОН**

127276 Москва, Ботаническая ул., 35, т.\ф (495) 231-2272 (499) 502-1214

**ООО "Медиклон"**

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**АВО, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**( ЦОЛИКЛОН Анти-Д Супер )**  
Регистрционное Удостоверение № ФСР 2009/066043 от 05 ноября 2009 г

**Наименование:** Цоликлон Анти-Д Супер во флаконах по 10 мл с зелеными крышками

**Серия:** 292711

**Емкость:** 100 мл

**Изготовлен:** 05.11.2019

**Количество единиц:** 40

**Годен до:** 05.11.2021

**Объем серии:** 10000 мл.

**Паспорт:** Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Д Супер не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступить в течение 30 сек. после смешивания реагента с D(-) эритроцитами	Соответствует 30 сек.
2.3 Тип	Тип Цоликлона Анти-Д Супер в реакции агглютинации на инкогости с D(+) эритроцитами 1:32 Тип Цоликлона Анти-Д Супер в реакции прямой агглютинации с D(+) эритроцитами в микротитре не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



ООО «Медиклон»

МЕДИКЛОН

127276 Москва, Ботаническая ул., 35, т.\ф (495) 231-2272 (499) 502-1214

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**АВО, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**( Ц О М И К Л О Н А Н Т И - Д ( Г р Г ) )**  
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

**Наименование:** Цоликлон Анти-D(GrG)

**Серия:** 292110

**Единица:** 100 мл

**Изготовлен:** 28.10.2019

**Количество единиц** 10

**Годен до:** 28.10.2021

**Объем серии:** 10000 мл.

**Паспорт:** Дж292110 от 28.10.2019

Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гематоглининирующая способность	Агглютинация эритроцитов D+ с Цоликлоном в пробирочном тесте с желатином должна появляться не позднее 15 мин.	Соответствует
2.3 Титр	Титр Цоликлона анти-D в пробирочном тесте с желатином 1:128. Титр Цоликлона в непрямом антиглобулиновом тесте: 1:512	Соответствует

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»



М.С.Орлова



ООО «Медиклон»

МЕДИКЛОН

127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

**П А С П О Р Т – С Е Р Т И Ф И К А Т П Р О И З В О Д И Т Е Л Я**  
**на «Набор реагентов для определения групп крови человека систем**  
**АВО, Резус и Келл» по ТУ-9398-101-51203590-2009**  
**( Ц О Л И К Л О Н Анти-Келл Супер)**  
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Келл Супер

Серия: 196410 Единица: 100 мл

Изготовлен: 21.10.2019 Количество единиц 10

Годен до: 21.10.2021 Объем серии: 10000 мл.

Паспорт: К196410 от 21.10.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
<b>2.1 Специфичность</b>		
	<b>Цоликлон Анти-Келл супер не должен агглютинировать эритроциты К(-)</b>	<b>Соответствует</b>
2.2 Гематогинирующая способность	Четкая реакция агглютинации на плоскости должна наступить в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Келл Супер в реакции прямой агглютинации в микроплане не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009  
Заведующая ОТК ООО «Медиклон»

М.С.Орлова





www.imq.it

**CERTIFICATO N. 0967.2019**  
**CERTIFICATE N.**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI  
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

**CERACARTA SPA**

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)  
SITI / SITES

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)  
E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

**ISO 14001:2015**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi tramite processo di stampaggio. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radiofrequenza (RFID) tramite processo di stampaggio. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG tramite processi di accoppiamenti delle materie prime e taglio a misura. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti  
*Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters*

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL  
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE  
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2019-06-05	2019-06-05	2022-06-04

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
Management Systems Division - Flavio Ornago



www.cisq.com



SGA N° 006 D

IAF: 07, 09, 19, 12, 29

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento  
Processes related to underlined IAF sectors are not yet covered by accreditation

Organismo di Certificazione Federato CISQ  
www.imq.it

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale  
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.  
CISQ is the Italian Federation of management system Certification Bodies.



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.  
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/IMQ** has issued an IQNet recognized certificate that the organization:

## **CERACARTA SPA**

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

*has implemented and maintains a  
Environmental Management System*

*for the following scope:*

*Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrodes for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters*

*which fulfills the requirements of the following standard:*

**ISO 14001:2015**

Issued on: **2019 - 06 - 05**

Expires on: **2022 - 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 - 125879



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

IQNet Partners\*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



# CERTIFICATO CE

Certificato n. 1976/MDD

## Dichiarazione di approvazione del sistema qualità

*(Garanzia di qualità della produzione)*

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

### **CERACARTA SPA**

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

mantiene negli stabilimenti di:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

#### **Carte per registrazione ad uso medico**

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.  
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:

DM17-0017248-01.

**Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.**

**Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.**

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ



IMQ S.p.A. - I-20138 Milano  
Via Quintiliano 43  
tel. + 39 0250731  
www.imq.it



# EC CERTIFICATE

Certificate No 1976/MDD

## Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

### CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factories of:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

#### Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.  
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:  
DM17-0017248-01.

**This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.  
Notified Body notified to European Commission under number: 0051.**

Date: 2017-11-18

Expiry Date: 2022-11-17

IMQ



This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

**This is a translation of the Italian text, which prevails in case of doubts**

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.  
 Materiale di consumo ed accessori elettromedicali.  
 Carte per apparecchi registratori industriali.  
 Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.  
 Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipment.  
 Disposable and electromedical accessories.  
 Chart Papers industrial recording instruments.  
 Special rolls and fanfolds for tickets checking systems.  
 lottery.  
 Rfid labels and chain solutions.

Sede (Head office and works) :  
 Via Secondo Casadei, 14 - 47122 FORLÌ - ITALY  
 Tel : 0039 0543 780055 • Fax : 0039 0543 781404  
 http : // [www.ceracarta.it](http://www.ceracarta.it) • e-mail : [info@ceracarta.it](mailto:info@ceracarta.it).  
 Capitale Sociale : € 1.000.000 int. vers.  
 Registro Imprese FORLÌ-CESENA  
 P.I. / C.F. / VAT.N. IT 00136740404  
 R.E.A. FORLÌ N. 72646 - N. MECC. FO 006863

**ELENCO CARTE DIAGRAMMATE CLASSE I F.M.**

**REV.15 - 16/10/2017**

Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

including the locations according to annex

Scope: Design and development, production and distribution  
of products for filtration, rapid tests, water analysis,  
chromatography and bioanalysis

Proof has been furnished by means of an audit that the  
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciennener Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

**mdc medical device certification GmbH**  
certifies that

**sifin**

**sifin diagnostics gmbh**  
**Berliner Allee 317-321**  
**13088 Berlin**  
**Germany**

for the scope

**development, manufacturing and distribution of  
in vitro diagnostic medical devices for the product groups:  
blood grouping, bacteriological test reagents and culture media as well as  
manufacturing of raw materials for manufacturing of  
in vitro diagnostic medical devices**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

**EN ISO 13485**

Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2018-10-23
Valid until	2021-10-22
Registration no.	D1058700042
Report no.	P18-00745-121758
Stuttgart	2018-07-16



Head of Certification Body






Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	VCA IgM CODE: VCAM.CE (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE(S)</b>	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
---------------------------	--

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – SEPTEMBER 2004
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013





Dia.Pro  
**Diagnostic**  
**BioProbes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HAV IgM</b> CODE: <b>AVM.CE</b> (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE(S)</b>	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
---------------------------	--

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – SEPTEMBER 2003
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013



Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	<b>HBc IgM</b> CODE: <b>BCM.CE</b> (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2004 03 0424 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	<p style="text-align: center;">DIA. PRO. DIAGNOSTIC BIOPROBES srl</p>

Rev: 12/2013



**LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS**  
*THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS*

**otorga el certificado número**  
*grants the certificate no.*

**2013 11 0039 EN**

**según la norma**  
*in accordance with the standard*

**UNE-EN ISO 13485:2018**

**(EN ISO 13485: 2016 & ISO 13485: 2016)**

**Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios**  
*Medical devices – Quality management systems - Requirements for regulatory purposes*

**a la empresa / to the company**

**Dia.Pro Diagnostic Bioprobes S.r.l.**

Sede social y de fabricación/ Headquarters and manufacturing facility

Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

**Para las siguientes actividades / For the following activities:**

**Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.**

**Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.**

*Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.*

*Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.*

**Modificaciones de alcance: Ver Anexo I / see Annex I**

**Fecha de validez/ Date of validity: Desde/ From: 8-03-2019 Hasta/To: 17-12-2021**

**Certificación inicial/ Initial certification date: 27-11-2013**

**Renovación / Renewal of certification date: 8-03-2019**

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://sede.aemps.gob.es>

Localizador: L P D T J L 5 2 D F



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 1 de 2

CERTIFICACIÓN 13485

C/ CAMPEZO, 1 - EDIFICIO 8  
28022 MADRID  
Tel.: (+34) 902.101.322 / (+34) 91.822.59.97  
Fax: (+34) 91.822.52.89

**ANEXO I / ANNEX I**

**CERTIFICADO UNE-EN ISO 13485:2018/ UNE-EN ISO 13485:2018 CERTIFICATE**

**Modificaciones del alcance / Scope modifications:**

<b>Fecha/Date</b>	<b>Descripción de la modificación/ Modification description</b>
<b>18-12-2018</b>	<p>Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico</p> <p><i>Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques). Change in the level of detail of the technological scope description.</i></p>
<b>8-03-2019</b>	<p>Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro".</p> <p>Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro".</p> <p><i>Extension of technological scope: Immunochemistry and Microbiology Instruments and software for "in vitro" diagnostic</i></p> <p><i>Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic</i></p>

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de  
medicamentos y  
productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://sede.aemps.gob.es>

Localizador: L P D T J L 5 2 D F





Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>CMV IgG</b> CODE: <b>CMVG.CE</b> (96 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST B
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MAY 2004
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – MAY 2018
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>CMV IgM</b> CODE: <b>CMVM.CE</b> (96 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST B
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MAY 2004
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – MAY 2018
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



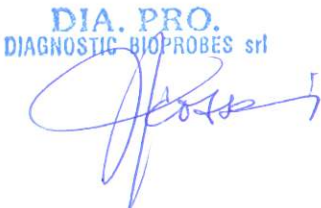
Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HCV IgM</b> CODE: <b>CVM.CE</b> (96 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2007 09 0532 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – SEPTEMBER 2007
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



**LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS**  
*THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS*

**otorga el certificado número**  
*grants the certificate no.*

**2013 11 0039 EN**

**según la norma**  
*in accordance with the standard*

**UNE-EN ISO 13485:2018**

**(EN ISO 13485: 2016 & ISO 13485: 2016)**

**Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios**  
*Medical devices – Quality management systems - Requirements for regulatory purposes*

**a la empresa / to the company**

**Dia.Pro Diagnostic Bioprobes S.r.l.**

Sede social y de fabricación/ Headquarters and manufacturing facility

Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

**Para las siguientes actividades / For the following activities:**

**Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.**

**Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.**

*Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.*

*Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.*

**Modificaciones de alcance: Ver Anexo I / see Annex I**

**Fecha de validez/ Date of validity: Desde/ From: 8-03-2019 Hasta/To: 17-12-2021**

**Certificación inicial/ Initial certification date: 27-11-2013**

**Renovación / Renewal of certification date: 8-03-2019**

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://sede.aemps.gob.es>

Localizador: L P D T J L 5 2 D F



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 1 de 2

CERTIFICACIÓN 13485

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Fax: (+34) 91.822.52.89

**ANEXO I / ANNEX I**

**CERTIFICADO UNE-EN ISO 13485:2018/ UNE-EN ISO 13485:2018 CERTIFICATE**

**Modificaciones del alcance / Scope modifications:**

<b>Fecha/Date</b>	<b>Descripción de la modificación/ Modification description</b>
<b>18-12-2018</b>	<p>Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico</p> <p><i>Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques). Change in the level of detail of the technological scope description.</i></p>
<b>8-03-2019</b>	<p>Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro".</p> <p>Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro".</p> <p><i>Extension of technological scope: Immunochemistry and Microbiology Instruments and software for "in vitro" diagnostic</i></p> <p><i>Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic</i></p>

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de  
medicamentos y  
productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://sede.aemps.gob.es>

Localizador: L P D T J L 5 2 D F






Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	<b>HDV IgM</b> CODE: <b>DIM.CE</b> (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2003 12 0395 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO DIAGNOSTIC BIOPROBES - srl

Rev: 12/2013





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2003 12 0390 ED</b>	<b>Desde/From 19/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: 62Y62AG59D

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

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ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/ <i>Certificate no</i>	Fecha de validez/ <i>Date of validity</i>	ON nº/ <i>NB no</i>
<b>2003 12 0390 ED</b>	Desde/ <i>From</i> <b>19/11/2018</b> Hasta/ <i>To</i> <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

**Clasificación/Classification:** Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)*  
[NANDO: IVD 0203]

**HBs Ab ELISA cualitativo-cuantitativo / ELISA qualitative-quantitative**

- SAB.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: 62Y62AG59D

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

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Página 2 de 2

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8

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**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2003 12 0391 ED</b>	<b>Desde/From 26/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: RP3FCJG870

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

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ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 11/12/2003  
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2003 12 0391 ED</b>	Desde/From <b>26/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

**Clasificación/Classification:** Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

**HBc Ab ELISA cualitativo / ELISA qualitative**

- BCAB.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: RP3FCJG870

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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ORGANISMO NOTIFICADO 0318

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**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2003 12 0392 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: B86E8DZ586

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

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ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 11/12/2003  
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2003 12 0392 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.**

**Dirección/Address: Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name: Idem Dirección/Address: Idem**

**Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.**

**Clasificación/Classification: Lista A, Anexo II / List A, Annex II**

**Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]**

**HCV Ab ELISA cualitativo / ELISA qualitative**

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests - for Dia.Blood application)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: B86E8DZ586

Fecha de la firma: 19/11/2018

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CORREO ELECTRÓNICO

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Página 2 de 2

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

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Fax: (+34) 91.822.52.89





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2003 12 0393 ED</b>	<b>Desde/From 19/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: GJEC8290C8

Fecha de la firma: 19/11/2018

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Página 1 de 2

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ORGANISMO NOTIFICADO 0318





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
<b>2003 12 0393 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

**Clasificación/Classification:** Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA) / *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)* [NANDO: IVD 0203]

**HDV Ab ELISA cualitativo / ELISA qualitative**

- DAB.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: GJEC8290C8

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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Página 2 de 2

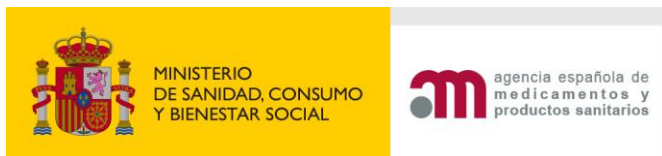
ORGANISMO NOTIFICADO 0318

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**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 15/03/2004  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2004 03 0425 ED</b>	<b>Desde/From 26/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: 3P6PS5XA6C

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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Página 1 de 2

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ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
in accordance with Annex IV, Section 4, Directive 98/79/EC  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 15/03/2004  
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2004 03 0425 ED</b>	Desde/From <b>26/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.**

**Dirección/Address: Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name: Idem Dirección/Address: Idem**

**Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.**

**Clasificación/Classification: Lista A, Anexo II / List A, Annex II**

**Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]**

**HBe Ag & Ab ELISA cualitativo / ELISA qualitative**

- HBE.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: 3P6PS5XA6C

Fecha de la firma: 23/11/2018

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Página 2 de 2

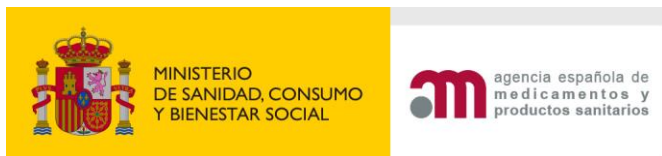
ORGANISMO NOTIFICADO 0318

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**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 04/12/2008  
Fecha de última prórroga/ Last extension date: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2008 12 0588 ED</b>	<b>Desde/From 19/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de  
medicamentos y  
productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: P6LLDBAA94

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

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ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: **04/12/2008**  
Fecha de última prórroga/ Last extension date: **27/11/2013**

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2008 12 0588 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.**

**Dirección/Address: Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name: Idem Dirección/Address: Idem**

**Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.**

**Clasificación/Classification: Lista A, Anexo II / List A, Annex II**

**Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]**

**HBs Ag one Version ULTRA ELISA cualitativo / ELISA qualitative**

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests - for Dia.Blood application)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de  
medicamentos y  
productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: P6LLDBAA94

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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ORGANISMO NOTIFICADO 0318

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Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	<b>HBe Ag&amp;Ab</b> CODE: <b>HBE.CE</b> (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2004 03 0425 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HP IgA</b> CODE: <b>HPA.CE</b> (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE(S)</b>	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MARCH 2004
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013




Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HP IgG</b> CODE: <b>HPG.CE</b> (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE(S)</b>	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MARCH 2004
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013






Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HP IgM</b> CODE: <b>HPM.CE</b> (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE(S)</b>	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – APRIL 2004
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HSV1&amp;2 IgG</b> CODE: <b>HSVG.CE</b> (96 tests)
<b>CLASSIFICATION</b>	GENERAL IVD
<b>CONFORMITY ASSESSMENT ROUTE</b>	SELF CERTIFICATION

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS  
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>ISO CERTIFICATE</b>	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MARCH 2004
<b>PLACE &amp; DATE OF CURRENT ISSUE</b>	SESTO SAN GIOVANNI (MI) – MARCH 2019
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



**GMED certifie que le système de management de la qualité développé par**  
*GMED certifies that the quality management system developed by*

**ELITECH CLINICAL SYSTEMS SAS**  
**Zone Industrielle**  
**61500 SEES FRANCE**

**pour les activités**  
*for the activities*

**Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.**

*Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.*

**réalisées sur le(s) site(s) de**  
*performed on the location(s) of*

**ELITech Clinical Systems SAS**  
**Zone industrielle - 61500 SEES - FRA**

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*

**NF EN ISO 13485 : 2016**

**Début de validité / Effective date : July 28th, 2020 (included)**

**Valable jusqu'au / Expiry date : July 27th, 2023 (included)**

**Etabli le / Issued on : July 17th, 2020**

**cofrac**

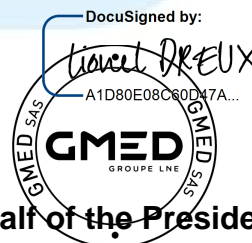


**CERTIFICATION DE SYSTEMES DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

GMED N° 10462-7

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-6



**On behalf of the President**  
**Lionel DREUX**  
**Certification Director**

## DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

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## DECLARATION OF EC CONFORMITY

*We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.*

*These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.*

*This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27<sup>th</sup>, 2023).*

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## DECLARACIÓN CE DE CONFORMIDAD

*Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.*

*Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.*

*Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).*

Sées, le 29 juillet 2020

**Valérie LAMBERT,**

Responsable des Affaires Réglementaires

*Regulatory Affairs Manager*

*Responsable de los Asuntos Reglamentarios*

**Cécile GOUBAULT,**

Directeur Général Délégué

*Managing Director*

*Directora General*

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
<b>Metabolites divers / Miscellaneous metabolites</b>		
ALBUMIN	ALBU-0600/0700/0250	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP SL	CRSL-0630/0250	53250
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPST-0850	
GLUCOSE HK SL	GHSL-0600/0250	53301
GLUCOSE PAP SL	GPST-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN ENVOY	PROB-0850	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA ENVOY	URSL-0850	53587
UREA UV SL	URSL-0407/0427/0420/0500/0507/0250/0455	
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	53583
URIC ACID SL	AUSL-0250	
<b>Enzymes / Enzymes</b>		
ALP (DEA) SL	PASL-0400/0420/0230	
ALP ENVOY	PIVD-0850	52928
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE ENVOY	AMSL-0850	52940
AMYLASE SL	AMSL-0390/0400/0230	
AST ENVOY	ASVD-0850	52954
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL	CMSL-0410/0430/0230	
CK NAC SL	CKSL-0410/0430/0230	53003
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53027
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH-L SL	LLSL-0400/0420/0230	
LIPASE ENVOY	LPSL-0850	53108
LIPASE SL	LPSL-0230	
<b>Electrolytes - Oligo-éléments / Electrolytes - Trace-elements</b>		
CALCIUM ARSENAZO	CALA-0600/0250	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
<b>Lipides / Lipids</b>		
CHOLESTEROL ENVOY	CHSL-0850	53359
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
HDL CHOLESTEROL	CHDL-0250/0600	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES ENVOY	TGML-0850	53460
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	
<b>Contrôles-Calibrants-Standards / Controls-Calibrators-Standards</b>		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
<b>Protéines spécifiques / Specific proteins</b>		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IIPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
<b>Vitamines/Vitamins</b>		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
<b>ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes</b>		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
<b>Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments</b>		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
<b>Tests d'agglutination / Agglutination tests</b>		
CRP LATEX	LXCR-0112	53707

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Queensway South  
Team Valley Trading Estate  
Gateshead  
Tyne and Wear  
NE11 0SD  
United Kingdom

Holds Certificate Number:

**MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14

Expiry Date: 2021-04-13



003

Page: 1 of 2

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Certificate No: **MD 69326**

Location

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Sunderland Enterprise Park  
Colima Avenue  
Sunderland  
SR5 3XB  
United Kingdom

Registered Activities

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Queensway South  
Team Valley Trading Estate  
Gateshead  
Tyne and Wear  
NE11 0SD  
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14

Expiry Date: 2021-04-13

Page: 2 of 2

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