



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

**РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**
от 22 января 2016 года № ФСР 2012/14183

На медицинское изделие
**Набор реагентов для клинического анализа спинномозговой жидкости
(«ДИАХИМ-ЛИКВОР») по ТУ 9398-067-27428909-2012**

Настоящее регистрационное удостоверение выдано
**Общество с ограниченной ответственностью "Научно-производственная фирма
"АБРИС+" (ООО "НПФ" АБРИС+), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж**

Производитель
**Общество с ограниченной ответственностью "Научно-производственная фирма
"АБРИС+" (ООО "НПФ" АБРИС+), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж**

Место производства медицинского изделия
192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье № РД-9561/60865 от 14.12.2015

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 22 января 2016 года № 841
допущено к обращению на территории Российской Федерации.

**Руководитель Федеральной службы
по надзору в сфере здравоохранения**



М.А. Мурашко

0035459

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 22 января 2016 года № ФСР 2012/14183

Лист 1

На медицинское изделие

**Набор реагентов для клинического анализа спинномозговой жидкости
(«ДИАХИМ-ЛИКВОР») по ТУ 9398-067-27428909-2012:**

- Реактив Самсона - готов к применению - 1 флакон 10 мл.
- Карболовая кислота - готов к применению - 1 флакон 2,5 г.
- Аммоний сернистый - готов к применению - 1 флакон (пакет) 85 г.

Z

Руководитель Федеральной службы
по надзору в сфере здравоохранения



М.А. Мурашко

0042330

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

**DICHIARA
DECLARES**

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

PUNTALI PER MICROPIPETTE TIPS FOR MICROPIPETTES DISPOSITIVI STERILI – STERILE DEVICES

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- > **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- > **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.
- > **Classificazione EDMA: 29011001 - Other Hardware + accessories + consumables + software**
EDMA code: 29011001 - Other Hardware + accessories + consumables + software
- > **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato / Released
Canelli, 27.11.2014

Duilio BEONO
Responsabile Assicurazione Qualità



ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	DESCRIPTION
10001/SG	Puntali macro tipo Finnpiquette, PP, neutro, 1000-10000µl	Macro tips Finnpiquette type, PP, neutral, 1000-10000µl
10005/SG	Puntali macro da 2.000 - 10.000 µl, colore neutro, modello BIOHIT	Macro tips 2,000 - 10,000 µl, neutral colour, BIOHIT type
1001/B/SG	Puntali per micropipette tipo Beckman, PP, neutro, 5-1000µl	Tips for micropipettes Beckman type, PP, neutral, 5-1000µl
1001/E/SG	Puntali per micropipette tipo Eppendorf, PP, blu, 101-1000µl	Tips for micropipettes Eppendorf type, PP, blue, 101-1000µl
1001/E/SG/CS	Puntali per micropipette tipo Eppendorf, PP, blu, 101-1000µl, sterile in confezione singola	Tips for micropipettes Eppendorf type, PP, blue, 101-1000µl
1001/G/SG	Puntali per micropipette tipo Gilson P500 P1000, PP, blu, 100-1000µl	Tips for micropipettes Gilson P500 P1000 type, PP, blue, 100-1000µl
1001/G/SG/CS	Puntali per micropipette tipo Gilson P500 P1000, PP, blu, 100-1000µl	Tips for micropipettes Gilson P500 P1000 type, PP, blue, 100-1000µl
1001/O/SG	Puntali per micropipette tipo Oxford, PP, verde, 101-1000µl	Tips for micropipettes Oxford type, PP, green, 101-1000µl
1001/OB/SG	Puntali per micropipette tipo Oxford, PP, blu, 101-1000µl	Tips for micropipettes Oxford type, PP, blue, 101-1000µl
1001/U/SG	Puntali per micropipette tipo universale, colore blu, 100-1000µl	Micropipettes tips universal type, blue colour, 100-1000µl
1001/UN/SG	Puntali neutri ad uso universale da 50-1000 µl, graduati, sterili	Universal tips neutral colour, 50-1000 µl, graduated, sterile
1002/U/SG	Puntali per micropipette tipo Eppendorf Universal, PP, neutro, 20-300µl graduate	Tips for micropipettes Eppendorf Universal type, PP, neutral, 20-300µl graduated
1025/U/SG	Puntali neutri ad uso universale da 50-1250 µl, graduati, sterili	Universal tips neutral colour, 50-1250 µl, graduated, sterile
10720	Puntali per gel da 0,1 - 20 µl, colore neutro, sterile in rack 96 pcs	Tips for gel loading 0.1-20 µl, neutral colour, sterile in rack of 96 pieces
1201/M/SG	Puntali per micropipette tipo MLA, PP, neutro, 101-1000µl	Tips for micropipettes MLA type, PP, neutral, 101-1000µl
1202/C/SG	Puntali per micropipette tipo Eppendorf-Cristall, PP, neutro, 0,5-10µl	Tips for micropipettes Eppendorf-Cristall type, PP, neutral, 0,5-10µl
1202/C/SG/CS	Puntali per micropipette tipo Eppendorf-Cristall, PP, neutro, 0,5-10µl	Tips for micropipettes Eppendorf-Cristall type, PP, neutral, 0,5-10µl
1202/E/SG	Puntali per micropipette tipo Eppendorf, PP, giallo, 5-200µl	Tips for micropipettes Eppendorf type, PP, yellow, 5-200µl
1202/E/SG/CS	Puntali per micropipette tipo Eppendorf, PP, giallo, 5-200µl, confezione singola.	Tips for micropipettes Eppendorf type, PP, yellow, 5-200µl, individually wrapped.
1202/G/SG	Puntali per micropipette tipo Gilson, PP, giallo, 5-200µl	Tips for micropipettes Gilson type, PP, yellow, 5-200µl
1202/G/SG/CS	Puntali per micropipette tipo Gilson, PP, giallo, 5-200µl	Tips for micropipettes Gilson type, PP, yellow, 5-200µl
1202/M/SG	Puntali per micropipette tipo MLA, PP, neutro, 5-200µl	Tips for micropipettes MLA type, PP, neutral, 5-200µl
1202/M/SG/CS	Puntali per micropipette tipo MLA, PP, neutro, 5-200µl	Tips for micropipettes MLA type, PP, neutral, 5-200µl
1202/MG/SG	Puntali per micropipette tipo Gilson P2 P10, PP, neutro, 0,5-10µl	Tips for micropipettes Gilson P2 P10 type, PP, neutral, 0,5-10µl
1202/OM/SG	Puntali per micropipette tipo Oxford, PP, neutro, 5-200µl	Tips for micropipettes Oxford type, PP, neutral, 5-200µl
1202/OM/SG/CS	Puntali per micropipette tipo Oxford, PP, neutro, 5-	Tips for micropipettes Oxford type, PP, neutral, 5-

Cod.	DESCRIZIONE	DESCRIPTION
	200µl	200µl
1202/U/SG	Puntali per micropipette tipo universale, colore giallo, 2-200µl graduati	<i>Micropipettes tips universal type, yellow colour, 2-200µl graduated</i>
1203/U/SG	Puntali tipo universale in PP, vol. 2-200 µl, graduati, neutri, sterili	<i>Micropipettes tips universal type, neutral colour, 2-200µl graduated</i>
1204/U/SG	Puntali tipo universale in PP, vol. 2-200 µl, gialli, sterili	<i>Micropipettes tips universal type, yellow colour, 2-200µl</i>
1302/B/SG	Puntali per micropipette tipo Biohit, PP, neutro, 2-300µl	<i>Tips for micropipettes Biohit type, PP, neutral, 2-300µl</i>
1302/G/SG	Puntali per micropipette tipo Gilson P20 P50 P100 P200, PP, neutro, 5-200µl graduate	<i>Tips for micropipettes Gilson P20 P50 P100 P200 type, PP, neutral, 5-200µl graduated</i>
1402/B/SG	Puntali tipo BIOHIT m-LINE/ PROLINE Plus, 0,1-10 µl, neutri, sterili	<i>Tips for micropipettes Biohit m-Line/Proline Plus type, PP, neutral, 0.1-10 µl</i>
1402/E/SG	Puntali per micropipette tipo Eppendorf, PP, neutro, 2-20µl	<i>Tips for micropipettes Eppendorf type, PP, neutral, 2-20µl</i>
1402/G/SG	Puntali per micropipette tipo Gilson, PP, gialle, 5-200µl beveled	<i>Tips for micropipettes Gilson type, PP, yellow, 5-200µl beveled</i>
1402/MG/SG	Puntali per micropipette tipo Gilson P2 P10, PP, neutro, 0,5-10µl lengthened	<i>Tips for micropipettes Gilson P2 P10 type, PP, neutral, 0,5-10µl lengthened</i>
1602/SG	Puntali per micropipette tipo Eppendorf cod 1202/E in refill-rack da 96pz., sterili	<i>Tips for micropipettes Eppendorf type cod. 1202/E in refill rack of 96 pieces, sterile</i>
1902/SG	Puntali per micropipette tipo Gilson cod 1202/MG in refill-rack da 96pz., sterili	<i>Tips for micropipettes Gilson type cod. 1202/MG in refill rack of 96 pieces, sterile</i>
19720	Puntali per gel sterili con filtro da 0,1 - 20 µl, colore neutro	<i>Tips for gel loading 0.1-20 µl, neutral colour, sterile with filter</i>
19730	Puntali per gel sterili con filtro da 0,1 - 100 µl, colore neutro	<i>Tips for gel loading 0.1-100 µl, neutral colour, sterile with filter</i>
4001/E/SG	Puntali per micropipette tipo Eppendorf cod. 1001/E, in rack da 96pz.	<i>Micropipettes tips Eppendorf type cod. 1001/E, in rack of 96 pcs.</i>
4001/G/SG	Puntali per micropipette tipo Gilson cod. 1001/G, in rack da 96pz.	<i>Micropipettes tips Gilson type cod. 1001/G, in rack of 96 pcs.</i>
4001/U/SG	Puntali per micropipette tipo universale, colore blu, 100-1000µl, rack da 96 pz	<i>Micropipettes tips universal type, blue colour, 100-1000µl, rack of 96 pcs</i>
4001/UN/SG	Puntali neutri ad uso universale da 50-1000 µl, graduati, in rack da 96 pcs sterile	<i>Universal tips neutral colour, 50-1000 µl, graduated, in racks of 96 pieces, sterile</i>
4002/U/SG	Puntali per micropipette tipo Universale cod. 1002/U, in rack da 96pz.	<i>Micropipettes tips Universal type cod. 1002/E, in rack of 96 pcs.</i>
4202/B/SG	Puntali neutri 1-300 µl in rack con coperchio, sterili	<i>Tips neutral colour 1-300 µl, in rack, sterile</i>
4202/C/SG	Puntali per micropipette tipo Eppendorf cod. 1202/C, in rack da 96pz.	<i>Micropipettes tips Eppendorf type cod. 1202/C, in rack of 96 pcs.</i>
4202/E/SG	Puntali per micropipette tipo Eppendorf cod. 1202/E, in rack da 96pz.	<i>Micropipettes tips Eppendorf type cod. 1202/E, in rack of 96 pcs.</i>
4202/G/SG	Puntali per micropipette tipo Gilson cod. 1202/G, in rack da 96pz.	<i>Micropipettes tips Gilson type cod. 1202/G, in rack of 96 pcs.</i>
4202/M/SG	Puntali per micropipette tipo MLA cod. 1202/M/SG, rack da 96 pz	<i>Micropipettes tips MLA type cod. 1202/M/SG, rack of 96 pcs</i>
4202/MG/SG	Puntali per micropipette tipo Gilson cod. 1202/MG, in rack da 96pz.	<i>Micropipettes tips Gilson type cod. 1202/MG, in rack of 96 pcs.</i>
4202/OM/SG	Puntali per micropipette tipo Oxford cod. 1202/OM/SG, rack da 96 pz	<i>Micropipettes tips Oxford type cod. 1202/OM/SG, rack of 96 pcs</i>
4202/U/SG	Puntali per micropipette tipo universale, colore giallo, 2-200µl graduati, rack da 96 pz.	<i>Micropipettes tips universal type, yellow colour, 2-200µl graduated, rack of 96 pcs</i>
4203/U/SG	Puntali tipo universale in PP, vol. 2-200 µl,	<i>Micropipettes tips universal type, neutral colour, 2-</i>

COD.	DESCRIZIONE	DESCRIPTION
	graduati, neutri, sterili	<i>200µl graduated, rack of 96 pcs</i>
4204/U/SG	Puntali tipo universale in PP vol. 2-200 µl, gialli, sterili	<i>Micropipettes tips universal type, yellow colour, 2-200µl, rack of 96 pcs</i>
4302/B/SG	Puntali per micropipette tipo Biohit cod. 1302/B, in rack da 96pz.	<i>Micropipettes tips Biohit type cod. 1302/B, in rack of 96 pcs.</i>
4302/G/SG	Puntali per micropipette tipo Gilson cod. 1302/G, in rack da 96pz.	<i>Micropipettes tips Gilson type cod. 1302/G, in rack of 96 pcs.</i>
4402/B/SG	Puntali tipo BIOHIT m-LINE/ PROLINE, vol.0,1-10µl, neutri, in rack sterili	<i>Tips for micropipettes Biohit m-Line/Proline Plus type, PP, neutral, 0.1-10 µl, sterile in rack 96 pcs</i>
4402/E/SG	Puntali per micropipette tipo Eppendorf cod. 1402/E, in rack da 96pz.	<i>Micropipettes tips Eppendorf type cod. 1402/E, in rack of 96 pcs.</i>
4402/G/SG	Puntali per micropipette tipo Gilson cod. 1402/G/SG, in rack da 96 pz	<i>Micropipettes tips Gilson type cod. 1402/G/SG, in rack of 96 pcs.</i>
4402/MG/SG	Puntali per micropipette tipo Gilson cod. 1402/MG, in rack da 96pz.	<i>Micropipettes tips Gilson type cod. 1402/MG, in rack of 96 pcs.</i>
5001/F/SG	Puntali macro tipo Finn timer, PP, neutro, 1000-5000µl	<i>Macro tips Finn timer type, PP, neutral, 1000-5000µl</i>
5001/O/SG	Puntali macro tipo Gilson, PP, blu, 1000-5000µl	<i>Macro tips Gilson type, PP, blue, 1000-5000µl</i>
5001/ON/SG	Puntali macro tipo Eppendorf, PP, neutro, 1000-5000µl	<i>Macro tips Eppendorf type, PP, neutral, 1000-5000µl</i>
6001/ON/SG	Puntali macro tipo Eppendorf, PP, neutro, 1000-5000µl, in rack sterile	<i>Macro tips Eppendorf type, PP, neutral, 1000-5000µ, sterile in rack</i>
9402	Puntali con filtro tipo BIOHIT m-LINE/ PROLINE Plus, 0,1-10 µl, neutri, in rack sterile	<i>Filter Tips for micropipettes Biohit m-Line/Proline Plus type, PP, neutral, 0.1-10 µl, sterile in rack</i>
9501	Puntali con filtro tipo Eppendorf, PP, neutro, 101-1000µl	<i>Filter tips. Eppendorf model, PP, neutral, 101-1000 µl</i>
9501/S	Puntali con filtro tipo Eppendorf, PP, neutro, 101-1000µl	<i>Filter tips. Eppendorf model, PP, neutral, 101-1000 µl</i>
9502	Puntali con filtro tipo Eppendorf, PP, neutro, 5-100µl	<i>Filter tips. Eppendorf model, PP, neutral, 5-100 µl</i>
9503	Puntali con filtro tipo Eppendorf Cristall, PP, neutro, 0,5-10 µl	<i>Filter tips. Eppendorf Cristall model, PP, neutral, 0,5-10 µl</i>
9503/S	Puntali con filtro tipo Eppendorf Cristall, PP, neutro, 0,5-10 µl	<i>Filter tips. Eppendorf Cristall model, PP, neutral, 0,5-10 µl</i>
9504	Puntali con filtro tipo Eppendorf, PP, neutro, 2-20µl	<i>Filter tips. Eppendorf model, PP, neutral, 2-20µl</i>
9504/S	Puntali con filtro tipo Eppendorf, PP, neutro, 2-20µl	<i>Filter tips. Eppendorf model, PP, neutral, 2-20µl</i>
9601	Puntali con filtro tipo Gilson, PP, neutro, 1-150 µl	<i>Filter tips. Gilson model, PP, neutral, 1-150 µl</i>
9603	Puntali con filtro tipo Gilson, PP, neutro, 1-100 µl	<i>Filter tips. Gilson model, PP, neutral, 1-100 µl</i>
9605	Puntali con filtro tipo Gilson, PP, neutro, 1-30 µl	<i>Filter tips. Gilson model, PP, neutral, 1-30 µl</i>
9606	Puntali con filtro tipo Gilson Universal, PP, neutro, 1-180 µl	<i>Filter tips. Gilson Universal model, PP, neutral, 1-180µl</i>
9610	Puntali con filtro tipo Gilson P2-P10, PP, neutro, 0,5-10 µl	<i>Filter tips. Gilson P2-P10 model, PP, neutral, 0,5-10µl</i>
9615	Puntali con filtro tipo Gilson, PP, neutro, 101-1000µl	<i>Filter tips. Gilson model, PP, neutral, 101-1000 µl</i>
9620	Puntali con filtro tipo Eppendorf, PP, neutro, 20-300µl, graduati.	<i>Filter tips. Eppendorf model, PP, neutral, 20-300 µl, graduated</i>
9620/S	Puntali con filtro tipo Eppendorf, PP, neutro, 20-300µl, graduati.	<i>Filter tips. Eppendorf model, PP, neutral, 20-300 µl, graduated</i>
9701	Puntali con filtro tipo universale, PP, neutro, 100-1000µl	<i>Filter tips universal type, PP, neutral, 100-1000µl</i>
9702	Puntali per gel, colore neutro, 0,1-200µl	<i>Tips for gel loading, neutral colour, 0,1-200µl</i>
9703	Puntali neutri con filtro ad uso universale da 50-1000 µl, graduati, sterili	<i>Universal tips with filter neutral colour, 50-1000 µl, graduated, sterile</i>

Cod.	DESCRIZIONE	DESCRIPTION
9710	Puntali con filtro tipo Gilson P2-P10, PP, neutro, 0,1-10µl	<i>Filter tips Gilson P2-P10 model, PP, neutral, 0,1-10µl</i>
9711	Puntali con filtro tipo universale, PP, neutro, 2-200µl	<i>Filter tips universal type, PP, neutral, 2-200µl</i>
9712	Puntali con filtro tipo Eppendorf Cristall, PP, neutro, 0,5-20 µl	<i>Filter tips. Eppendorf Cristall model, PP, neutral, 0,5-20 µl</i>
9713	Puntali con filtro tipo universale, vol. 2-100 µl, neutri, sterili in rack	<i>Filter tips. universal model, PP, neutral, 2-100 µl</i>
9801	Puntali macro con filtro da 1.000 - 5.000 µl, colore blu, modello GILSON	<i>Macro tips with filter 1,000 - 5,000 µl, blue colour, GILSON type</i>
9802	Puntali macro con filtro da 1.000 - 5.000 µl, colore neutro, modello EPPENDORF	<i>Macro tips with filter 1,000 - 5,000 µl, neutral colour, EPPENDORF type</i>
9803	Puntali macro con filtro da 1.000 - 5.000 µl, colore neutro, modello FINNPIPETTE	<i>Macro tips with filter 1,000 - 5,000 µl, neutral colour, FINNPIPETTE type</i>
9810	Puntali macro con filtro da 2.000 - 10.000 µl, colore neutro, modello GILSON	<i>Macro tips with filter 2,000 - 10,000 µl, neutral colour, GILSON type</i>
9811	Puntali macro con filtro da 2.000 - 10.000 µl, colore neutro, modello BIOHIT	<i>Macro tips with filter 2,000 - 10,000 µl, neutral colour, BIOHIT type</i>
9920/B	GreenTip® Puntali neutri 0,1-10 µl sterile, con filtro, tipo UNIVERSALE, in rack PP biodegradabile	<i>GreenTip® Filter Tips universal type 0.1-10 µl, PP, neutral colour, in biodegradable rack</i>
9921/B	GreenTip® Puntali neutri 2-100 µl, sterile con filtro, tipo UNIVERSALE, in rack PP biodegradabile	<i>GreenTip® Filter Tips universal type 2-100 µl, PP, neutral colour, in biodegradable rack</i>
9922/B	GreenTip® Puntali neutri 2-200 µl, sterile con filtro, tipo UNIVERSALE, in rack PP biodegradabile	<i>GreenTip® Filter Tips universal type 2-200 µl, PP, neutral colour, in biodegradable rack</i>
9923/B	GreenTip® Puntali neutri 100-1000 µl, sterile con filtro tipo UNIVERSALE, in rack PP biodegradabile	<i>GreenTip® Filter Tips universal type 100-1000 µl, PP, neutral colour, in biodegradable rack</i>

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che i Dispositivi Medici di seguito descritti:
That Medical Devices described as follows:

**TAMPONI PER LA RACCOLTA E LA CONSERVAZIONE DI CAMPIONI
BIOLOGICI, ANCHE IN AMBITO CHIRURGICO, CON O SENZA TERRENO DI
TRASPORTO**

**MEDICAL SWABS AND APPLICATORS FOR BIOLOGICAL SAMPLE
COLLECTION AND PRESERVATION, ALSO FOR SURGERY USE, WITH OR
WITHOUT TRANSPORT MEDIUM**

PRODOTTI STERILI – STERILE PRODUCTS

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- Sono conformi ai requisiti essenziali di cui all'allegato I della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE.
They are conform to the essential requirements of Annex I of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC
- Sono classificati di Classe IIa sterile in base all'Allegato IX - regola 6 - p.to 2.2. della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE.
They are classified as Class IIa sterile according to Annex IX - Rule 6 - p.t 2.2. of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC
- Sono soggetti a marcatura CE rilasciata dall'Organismo Notificato n° 0426 Italcert Srl
They are subject to CE mark issued by the Notified Body n° 0426 Italcert Srl
- Sono prodotti con un Sistema Qualità della produzione conforme all'Allegato V della Direttiva 93/42/CE
They are manufactured with a production quality system in accordance with Annex V of Directive 93/42/EC

Tale dichiarazione è supportata dalla certificazione del Sistema Qualità Nuova Aptaca secondo gli standard UNI EN ISO 9001 e UNI EN ISO 13485

This statement is supported by the New Aptaca Quality System Certification according to UNI EN ISO 9001 and UNI EN ISO 13485

Rilasciato / Released
Canelli, 13.05.2014

Dulio BEONO
Responsabile Assicurazione Qualità



ALLEGATO 1 alla Dichiarazione di Conformità Tamponi sterili

Annex 1 to Declaration of Conformity Sterile Swabs

Cod.	DESCRIZIONE	DESCRIPTION
2150/SG	Tamponi sterili puntale in cotone ed asta in legno, in provetta PP, sterili	<i>Sterile swabs cotton tip and wooden stick, in PP test tubes, sterile</i>
2150/SG/CS	Tamponi sterili puntale in cotone ed asta in legno, in provetta PP, sterili in confezione singola	<i>Sterile swabs cotton tip and wooden stick, in PP test tubes, sterile individually wrapped</i>
2160/SG	Tamponi sterili puntale in viscosa ed asta in plastica, in provetta PP, sterili	<i>Sterile swabs rayon tip and plastic stick, in PP test tubes, sterile</i>
2160/SG/CS	Tamponi sterili puntale in viscosa ed asta in plastica, in provetta PP, sterili in confezione singola	<i>Sterile swabs rayon tip and plastic stick, in PP test tubes, sterile individually wrapped</i>
2170/SG	Tamponi sterili puntale in viscosa ed asta in alluminio, in provetta PP, sterili	<i>Sterile swabs rayon tip and aluminium stick, in PP test tubes, sterile</i>
2170/SG/CS	Tamponi sterili puntale in viscosa ed asta in alluminio, in provetta PP, sterili in confezione singola	<i>Sterile swabs rayon tip and aluminium stick, in PP test tubes, sterile individually wrapped</i>
301/SG	Tamponi sterili con terreno di trasporto Amies senza carbone, asta in plastica, in provetta PP	<i>Sterile swabs with clear Amies medium, plastic stick, in PP test tubes</i>
301/AL/SG	Tamponi sterili con terreno di trasporto Amies senza carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with clear Amies medium, aluminium stick, in PP test tubes</i>
303/SG	Tamponi sterili con terreno di trasporto Amies con carbone, asta in plastica, in provetta PP	<i>Sterile swabs with Amies medium with charcoal, plastic stick, in PP test tubes</i>
303/AL/SG	Tamponi sterili con terreno di trasporto Amies con carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with Amies medium with charcoal, aluminium stick, in PP test tubes</i>
305/SG	Tamponi sterili con terreno di trasporto Stuart senza carbone, asta in plastica, in provetta PP	<i>Sterile swabs with clear Stuart medium, plastic stick, in PP test tubes</i>
305/AL/SG	Tamponi sterili con terreno di trasporto Stuart senza carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with clear Stuart medium, aluminium stick, in PP test tubes</i>
307/SG	Tamponi sterili con terreno di trasporto Stuart con carbone, asta in plastica, in provetta PP	<i>Sterile swabs with Stuart medium with charcoal, plastic stick, in PP test tubes</i>
307/AL/SG	Tamponi sterili con terreno di trasporto Stuart con carbone, asta in alluminio, in provetta PP	<i>Sterile swabs with Stuart medium with charcoal, aluminium stick, in PP test tubes</i>
309/SG	Tamponi sterili con terreno di trasporto Cary Blair, asta in plastica, in provetta PP	<i>Sterile swabs with Cary Blair medium, plastic stick, in PP test tubes</i>

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).

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 27th, 2023).

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 12 Mai 2021

Valérie LAMBERT,

Responsable des Affaires Réglementaires

Regulatory Affairs Manager

Responsable de los Asuntos Reglementarios



ELITech Clinical Systems SAS

Zone Industrielle

61500 SEES - France

Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

SIRET 318 365 228 00036

Cécile GOUBAULT,

Directeur Général Délégué

Managing Director

Directora General



Société par actions simplifiée au capital de 1.688.392,33 € – SIREN : 318 365 228 – RCS ALENCON

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	
ALBUMIN ENVOY	ALBU-0850	53597
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	CRSL-M490	
CREATININE PAP SL	CRSL-0630/0250	53250
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPST-0850	
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	53301
GLUCOSE PAP	GPST-M690	
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/M430	
PHOSPHORUS ENVOY	PHOS-0850	59123
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	
TOTAL PROTEIN ENVOY	PROB-0850	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	
UREA ENVOY	URSL-0850	53587
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	53583
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	
ALP ENVOY	PIVD-0850	52928
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	52923
AMYLASE	AMSL-M430	
AMYLASE ENVOY	AMSL-0850	52940
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	
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 / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	
CK NAC SL	CKSL-0410/0430/0230	53003
GAMMA-GT	GISL-M230	
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53027
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	
LDH IFCC	LLSL-M230	53072
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	
LIPASE ENVOY	LPSL-0850	53108
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-éléments / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	
CALCIUM ENVOY	CALA-0850	45789
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	
IRON FERENE	FEFE-0230/0600/M230	54758
MAGNESIUM ENVOY	MAGX-0850	
MAGNESIUM XB	MGXB-0250/0600/M430	46795
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	
CHOLESTEROL ENVOY	CHSL-0850	53359
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	
HDL CHOLESTEROL ENVOY	HDLL-0850	53391
LDL CHOLESTEROL	CLDL-0250/M330	
LDL CHOLESTEROL ENVOY	LDLL-0850	53395
TRIGLYCERIDES	TGML-M690	
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	53460
TRIGLYCERIDES SL	TGML-0250/0455	

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REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
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
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	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	IPRO-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
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
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	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
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	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

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EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
LE Latex test kit	840050

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies 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).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



CERTIFICATE

EC No 1434-IVDD-134/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

**Unit 1 Cutbush Park Industrial Estate, Danehill,
Lower Earley, Berkshire RG6 4UT, United Kingdom**

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 649/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-134/2019**
Issued under the Contract No **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019



ANNEX 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-134/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593




mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-134/2019**
Issued under the Contract No. **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019



Medica Corporation
 5 Oak Park Drive
 Bedford, Massachusetts 01730
 Tel 781 275 4892
 Fax 781 275 2731
 www.medicacorp.com

Products For Health Care

Declaration of Conformity **CE**

Product Name:

EasyLyte and accessories per attachment

EasyElectrolyte and accessories per attachment

EasyStat and accessories per attachment

EasyBloodGas and accessories per attachment

Model/Type:

EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH

EasyElectrolyte Na/K/Cl, Na/K/Li

pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct

pH/pCO2/pO2

Manufacturer

 Medica Corporation
 5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Molenstraat 15
 NL-2513 BH The Hague, The Netherlands
 Tel: +31 70 345 8570
 Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

Place and Date: Bedford, Massachusetts, USA, March 1, 2012

Signature:



Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO ₂ Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO ₂ Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenance Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

от 05 ноября 2009 года

Настоящее регистрационное удостоверение выдано

Обществу с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
и подтверждает, что медицинское изделие

Набор реагентов для определения групп крови человека систем ABO,
Rезус и Kell (Цоликлоны анти-A, анти-B, анти-AB, анти-A1, анти-Асл,
анти-D супер, анти-D (IgG), анти-C супер, анти-с супер, анти-E супер,
анти-е супер, анти-Kell супер) по ТУ 9398-101-51203590-2009
производства

Обществу с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
место производства:

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1

класс потенциального риска 2а

ОКП 93 9816

вид медицинского изделия –

соответствующее регистрационному досье № 67875 от 22.09.2009

приказом Росздравнадзора от 05 ноября 2009 года № 8861-Пр/09

и приказом от 17 июля 2013 года № 3237-Пр/13 с замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

М.А. Мурашко

0001849



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

Лист 1

№ ФСР 2009/06043

- цоликлон анти-A - моноклональные антитела (IgM) к антигену A;
- цоликлон анти-B - моноклональные антитела (IgM) к антигену B;
- цоликлон анти-AB - моноклональные антитела (IgM) к антигенам A и B;
- цоликлон анти-A1 - фитогемагглютинин к антигену A1;
- цоликлон анти-Асл - моноклональные антитела (IgM) к антигенам A1 и A2;
- цоликлон анти-D супер - моноклональные антитела (IgM) к антигену D;
- цоликлон анти-D (IgG) - моноклональные антитела (IgG) к антигену D;
- цоликлон анти-C супер - моноклональные антитела (IgM) к антигену C;
- цоликлон анти-с супер - моноклональные антитела (IgM) к антигену с;
- цоликлон анти-E супер - моноклональные антитела (IgM) к антигену E;
- цоликлон анти-е супер - моноклональные антитела (IgM) к антигену е;
- цоликлон анти-Kell супер - моноклональные антитела (IgM) к антигену K;

≡

Приказом от 17 июля 2013 года № 3237-Пр/13 с досье допущено к обращению на
территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

М.А. Мурашко

05 ноября 2009 года

0001890





SYSTEM OF
INTERNATIONAL
CERTIFICATION

СЕРТИФИКАТ

на систему менеджмента качества

SIC.MS.094.ISO13485.1332 от 11.03.2020 до 10.03.2023

Орган сертификации "Международное Агентство Сертификации"
настоящим сертификатом подтверждает, что система менеджмента
качества

«Медиклон»

Общество с ограниченной ответственностью

127276 Российская Федерация, Москва, ул. Ботаническая, дом 35

Применительно к

производству изделий медицинского назначения, а
именно: «Реагентов и наборов реагентов для
определения групп крови человека систем ABO Резус и
Келл, а также антигенов и антител системы Резус»

соответствует требованиям международного стандарта

EN ISO 13485:2016

**"Изделия медицинские. Системы менеджмента качества.
Системные требования для целей регулирования"**

Дата сертификации:

11.03.2020 г.

Действителен до:

10.03.2023 г.

при условии ежегодного подтверждения
2021 г. - до 11.02.2021
2022 г. - до 11.02.2022

Руководитель органа



Т.Р. Погребная



SIC.MS.094.ISO13485.1332

ОС «Международное Агентство Сертификации», свидетельство Нотификации:

SIC.CB.643.094 от 21.03.2019 г., 109444, Российская Федерация, г. Москва, б-р Самаркандский, д.10,

корпус 1, кв. 62, Тел./Факс: +7(903) 223-25-69, выданный S.I.C. Global Inc., 346 WIGSTON DR, Suite 4, NORTH BAY, ONTARIO, P1A 1X3, CANADA

<http://sic.com.ua>

Declaration of Conformity



Certificate Identification: SC-08H59
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 	Signature: 
Full Name: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>18 June 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V5</u> <u>February 26, 2015</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity



Certificate Identification: SC-01H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	<u>Barry Simpson</u>	Full Name:	<u>Marcy Jaqua</u>
Position:	<u>Site Quality Manager</u>	Position:	<u>Director, Regulatory Affairs</u>
Date of Approval:	<u>29 Jun 2015</u>	Date of Approval:	<u>30 June 2015</u>
Date Issued:	<u>JUN 30 2015</u>	Place Issued:	<u>Abbott Santa Clara</u>
Supersedes:	<u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number):	<u>JUL 06 2015</u>

Declaration of Conformity

Certificate Identification: SC-99644
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared

Authorized European Representative (name and address)	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:  Full Name: <u>Barry Simpson</u> Position: <u>Quality Manager</u> Date of Approval: <u>04. Sept. 2015</u> Date Issued: <u>SEP 04 2015</u> Supersedes: <u>IRIS V4, January 10, 2014</u>	Signature:  Full Name: <u>Marcy Jaqua</u> Position: <u>Regulatory Affairs, Director</u> Date of Approval: <u>04 Sep 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>SEP 11 2015</u>
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Declaration of Conformity


Certificate Identification: SC-03H80
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 	Signature: 
Full Name: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun. 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity

Certificate Identification: SC-08H52
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:  Full Name: <u>Barry Simpson</u> Position: <u>Site Quality Manager</u> Date of Approval: <u>29 Jun 2015</u> Date Issued: <u>JUN 30 2015</u> Supersedes: <u>IRIS V2, January 10, 2014</u>	Signature:  Full Name: <u>Marcy Jaqua</u> Position: <u>Director, Regulatory Affairs</u> Date of Approval: <u>30 June 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>JUL 06 2015</u>
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