Digitally signed by Poiata Vitalie
Date: 2021.07.15 15:47:12 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr.7.2 la Instrucțiunea aprobată prin ordinul IFPS nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2112093 **din** / от 14.07.2021

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 29.07.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani a DGAF mun.Chișinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUȘ
Numele și prenumele/Фамилия и имя

L.Ș./M.П.

Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 14.07.2021 ora 15:14:25 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8506** din **28.04.2021**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albişoara, 16/1, ap.(of.) 7, mun. Chişinău, Republica Moldova.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

1. POIATA VITALIE 33,40 %

2. NASEDCHIN ALEXANDR 33,30 %

3. KOJEVNIKOV DMITRII 33,30 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Fecal Occult Blood (FOB) Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	5
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC03/02

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	H.Pylori Ag Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	4
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC02/06

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Anti-HBs Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Annex II List A, 98/79/EC
Conformity Assessment Route:	Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Notified Body:	Polish Centre for Testing and Certification (PCBC), ul. Klobucka 23a 02-699 Warszawa Poland (Notified Body # 1434)
Start of CE Marking:	29.08.2008
Revision No:	7
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE 1434

DOC02/04

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Troponin I Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	4
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC04/01

CERTIFICATE

No J - 2670/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cells reagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:47:33 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No J - 2670/4/2020

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:48:40 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

SOĞUK DAMGA VARDIR

TERCÜME

T.C. TORBALI 6. NOTERLİĞİ Tel: 0232 854 70 07 Fax: 0232 854 70 17

№09971

SERTİFİKA

No. M – 56/4/2020

İşbu sertifika ile;

TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No:2, Tekeli-Menderes
İzmir, Türkiye

ve sertifika ekinde listelenmiş

Lokasyon

Aşağıdaki faaliyetler kapsamında

EN ISO 13485:2016

ile uyumludur:

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kendi kendine test ve profesyonel kullanım için tasarlanmış hızlı testler, kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri) ve EKG elektrotları

Polonya Test ve Sertifikasyon Merkezi tarafından yürütülen denetim, yukarıdaki kanıtları sağlamıştır. Bu Sertifika, Kuruluş tarafından yukarıdaki standarda uyulması kaydıyla geçerliliğini koruyacaktır.

Bu sertifikanın geçerlilik tarihi: 22.12.2020'den 21.12.2023'e kadar

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020
Sertifika kararının tarihi: 14.10.2020
Sertifika, yetkili imzayı taşımaktadır.
Varşova, 15.10.2020

Anna Małgorzata Wyroba <<Elektronik İmza>>
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C. TORBALI 6. NOTERİ Selma ZİYREK

SOĞUK DAMGA VARDIR

№09971

CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

T.C. TORBALI 6. NOTERİ Selma ZİYREK

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:00:16 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

TERCÜME

№09971

SERTİFİKA EKİ

SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR

No. M – 56/4/2020

İşbu sertifika, aşağıda yer alan faaliyetler kapsamındaLokasyonun tasdiki için hazırlanmıştır:

Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-MenderesİZmir, Türkiye

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri), profesyonel kullanım IVD testleri ve EKG elektrotları

Sertifikada listelenen standardın gereksinimlerini karşılar.

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020
Sertifika kararının tarihi: 14.10.2020
Sertifika, yetkili imzayı taşımaktadır.
Varşova, 15.10.2020

Anna <<Elektronik İmza>>
Małgorzata
Wyroba
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
ZİYREK

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

№09971

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Page 1 of 1

CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:00:16 +02'00'
Member of the Board

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Page 1 of 1

CERTIFICATE

EC No 1434-IVDD-432/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 59/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-432/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-433/2019
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:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

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 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 59/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-433/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-430/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 58/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-430/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Klobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-431/2019
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:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

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 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 58/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-431/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Klobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-436/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

Anti-HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 57/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-436/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-437/2019
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:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

Anti-HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

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 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 57/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-437/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-434/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 56/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-434/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-435/2019
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:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

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 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 56/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-435/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza De La Verneda 1,
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and sale of sterile and nonsterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.
Distribution of non-active medical devices and in vitro diagnostic medical devices.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.
Distribución de productos sanitarios no activos y productos sanitarios para diagnóstico in vitro.

This certificate is valid from 11 October 2019 until 11 October 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 September 2022
Issue 9. Certified since 12 October 2010

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Certificate ES16/20725

The management system of

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis, general labware, containers and healthcare products. Manufacture and commercialization of consumables for the laboratory. Commercialization and distribution of equipment for the storage of prepared samples, cryogenic stored samples, syringes, general labware and industrial packages. Commercialization and distribution of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes. Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

This certificate is valid from
11 October 2019 until 11 October 2022.
Issue 4. Company certified since October 2010.
Certified with SGS since 11 October 2016.

This is a multisite certification. See following page(s).

Authorised by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

Certificate ES16/20725

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

ISO 9001:2015

Issue 4

Sites where these activities are totally or partially carried out

DELTALAB, S.L.
Pol. Ind. La Llana, Plaza de la Verneda, 1 – 08191 Rubí, Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

KEYLAB, S.L.U.
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

NIRCO, S.L.
Pol. Ind. Expansión, Puerto de Navafría, 12 - 28935 Móstoles -Madrid (España)
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Manufacture and commercialization of consumables for the laboratory.
Commercialization and distribution of diagnostic kits
Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

ENVASES FARMACÉUTICOS, S.A.
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Design, manufacture and commercialization of laboratory material for the collection, transport and conservation of samples for analysis, laboratory material for general use, containers and products for personal care
Commercialisation and distribution of laboratory material for general use, products and equipment for personal care, syringes and cosmetic products.

Certificate ES16/20725.01

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP certified organization as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages. Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubi (Barcelona)

Valid from
11 October 2019 until 11 October 2022.
Issue 1.

This document Is part of Certificate ES16/20725.
The validity of this document is subject to the certificate.

CERTIFICACIÓN
Nº 05 / C - SC001

Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

[State seal]
MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

Agencia Española de Medicamentos y Productos Sanitarios
[Spanish State Agency of Medication and Sanitary Products]

S/REF
N/REF: PS/DP/MST
Date: 01/12/2015
Subject: Information to the addressee

DELTALAB, S.L
PLAZA DE LA VERNEDA, 1
POLIGONO INDUSTRIAL LA LLANA
081191 RUBÍ
(BARCELONA)

In response to your email dated 24/11/2015 requesting information on the products detailed below, which are included as items for general laboratory use in your company´s catalogue, and after having made the relevant inquiries, I can inform you that:

- Slides
- Uncoated cover slides
- Pasteur pipettes
- Tips for general purpose pipettes
- Sample cups and cuvettes
- Spreaders for extensions
- Calibrated loops
- Petri dishes
- Vials
- Caps
- Serological pipettes
- Cryovials
- Ritips
- Cassettes for biopsy
- Microtitre plates
- E.S.R. system stands
- Anticoagulants and preservatives in bulk
- Stains for microbiology.

[State seal]
MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY
SUPPORTING RECORD
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
[SPANISH STATE AGENCY OF MEDICATION AND SANITARY PRODUCTS]
EXIT
Registration No: 26082/RG53761
Date; 14/12/2015 09:24:32

These products do not fall under the scope of Royal Decrees 1591/2009 of 16 October and 1662/2000 of 29 September, which regulate medical devices and medical devices for in vitro diagnostics respectively. These decrees transpose Directive 93/42/EEC on medical devices and Directive 98/79/EC of the European Parliament and of the Council dated 27 October 1998 on in vitro diagnostic medical devices to Spanish legislation, therefore their marketing falls under commercial legislation, consumer and user protection legislation and any applicable specific legislation.

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS
[Illegible signature]
Mª del Carmen Abad Luna
[Seal: Spanish State Agency of Medication and Sanitary Products]
Page 1/1

EMAIL
mpizarro@aemps.es

C/CAMPEZO, 1-EDIFICIO 8
28022 MADRID
TELEPHONE: 91 822 52 61
FAX: 91 822 52 89

Doña Marta Casanova Hernández, Traductora e Intérprete jurada de inglés nombrada por el Ministerio de Asuntos Exteriores y Cooperación certifica que la que antecede es traducción fiel y completa al inglés de un documento redactado en español.
En Salamanca, a 15 de diciembre de 2015

I, Marta Casanova, Sworn Translator and Interpreter of English named by the Ministry of Foreign Affairs and Cooperation, hereby certify that the foregoing is a true and complete translation into English of a document written in Spanish.
In Madrid, 15 December 2015

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS
Nº 9494

Declaración de Conformidad "CE"
"CE" Declaration of conformity

Directiva Productos Sanitarios para el Diagnóstico In Vitro 98/79/CE
In Vitro Diagnostic Medical Devices Directive 98/79/EC

Fabricante / *Manufacturer:* **AQUISEL, s.l.**
Dirección / *Address:* Autovía A-2 Km 585,1 08630 ABRERA (BARCELONA) - SPAIN

Declara bajo su responsabilidad que los productos listados debajo, han estado diseñados para la aplicación de diagnóstico In Vitro y cumplen todos los requisitos esenciales del anexo I del Real Decreto 1662/2000 transposición a la Legislación Española de la Directiva 98/79/CE sobre productos sanitarios para diagnóstico In Vitro.

Declares under their responsibility that the products listed below have been designed for In Vitro diagnostic application and that they comply with all essential requirements as laid out in Annex I of Real Decreto 1662/2000 transposition to the Spanish Legislation of the Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

"Tubos AQUISEL"; contenedores para la recogida de muestras de sangre, variantes:
The "AQUISEL tube"; containers for blood sampling collection, kinds:

• K3E/EDTA 3K (anticoagulante)	• *K3E/EDTA 3K (anticoagulant)*
• K2E/EDTA 2K (anticoagulante)	• *K2E/EDTA 2K (anticoagulant)*
• 4NC/CITRATO 3Na (anticoagulante)	• *4NC/Citrate 3Na (anticoagulant)*
• 9NC/CITRATO 3Na (anticoagulante)	• *9NC/Citrate 3Na (anticoagulant)*
• LH/Heparina Li (anticoagulante)	• *LH/Li Heparin (anticoagulant)*
• LH/Heparina Li – Gel (anticoagulante)	• *LH/Li Heparin + Gel (anticoagulant)*
• MonoiodoAcetato Li +Gránulos PS activador (antiglicolítico)	• *IodoAcetate Li + Granules activator (antiglycolitic)*
• LH/Heparina Li + MonoiodoAcetato Li (anticoagulante + antiglicolítico)	• *LH/Li Heparin + IodoAcetate Li (anticoagulant + antiglycolitic)*
• FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante)	• *FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant)*
• Z/Vacío (sin aditivos)	• *Z/Empty (non additive)*
• Z/ Tubo tratado (para suero)	• *Z/ Treatment Tube (for serum)*
• Z/ Tubo tratado con Gel separador (para suero)	• *Z/ Treatment Tube with Separator Gel (for serum)*
• Z/ Tubo tratado con Gránulos PS (para suero)	• *Z/ Treatment Tube with Granules PS (for serum)*
• Z/ Tubo con activador de la coagulación (para suero)	• *Z/ Tube with clotting activator (for serum)*
• Z/ Tubo con activador + Gel separador (para suero)	• *Z/ Tube with clotting activator + Separator Gel (for serum)*
• Z/ Tubo con activador + Gránulos PS (para suero)	• *Z/ Tube with clotting activator + Granules PS (for serum)*
Accesorios	***Accessories***
• CAP-GALET (Embudo para muestras de sangre)	• *CAP-GALET (Funnels for Blood Sampling)*

Abrera a 09 Octubre de 2014 , *Abrera 09th October 2014*

Firmado/Signed : Manel Sotelo y Sotelo
(Gerente / Manager)

file.:TF-1101-F _10-2014

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer:*

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL DE TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE MARCA EUROTUBO
INVASIVE STERILE EUROTUBO COLLECTION SWAB FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM
(Códigos según Anexo 1 / *Codes in Annex 1)*

Tipo: Sistema invasivo estéril de recogida de muestras por contacto directo con el paciente
Type: *Invasive sterile collection system by direct contact with the patient*

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos
Intended Use*: Collection and transport of biological samples for subsequent microbiological analysis*

Código GMDN / *GMDN Code:* 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

<u>ESCOBILLON - *Swab*</u>

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en **Real Decreto 1591/2009.**
Directive 93/42/ECC *Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1591/2009.***

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL
En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número <u>2005 06 0474 CP Epígrafe 1</u>, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:
Regarding the swabs, this documentation is supported by the CE Certificate number <u>2005 06 0474 CP Epigraph 1</u>, Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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<u>TUBO CON MEDIO DE TRANSPORTE – *Tube with transport medium*</u>

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.
Transposición a la legislación española en **Real Decreto 1662/2000.**
Directive 98/79/EC *In vitro Diagnostic Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1662/2000.***

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab
DELTALAB S.L
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubí - Barcelona

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
300200	ESCOBILLON MAD.+ALGODON PEEL/1	SWAB I/W PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB I/W PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB I/W PEEL/1 PS+VISCOSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB I/W PEEL ALUM+COTTON
300210	ESCOBILLON MAD.+ALGOD.B/2 PEEL	SWAB B/2 PEEL/2 WOOD+COTTON
300250	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300251	ESCOBILLON ALU.+ALGODON TUBO	SWAB IN TUBE ALUM+COTTON
300252	ESCOBILLON PS+VISCOSA TUBO	SWAB IN TUBE PS+VISCOSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSE
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLÓN 13X165MM PS C/POLIÉSTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300290	STUART MADERA+ALGODÓN	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODÓN	STUART SWAB ALUM+COTTON
300292	STUART ALUMIN.TRENZADO+VISCOSA	STUART SWAB TWISTED ALU + VISC
300294	VIRUS ALUMINIO + POLIESTER	VIRUS SWAB ALUMINIUM POLYESTER
300295	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIESTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIESTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+VISCOSE SWAB FLOW

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REF	DESCRIPCIÓN	*DESCRIPTION*
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSE
300250.1	ESCOBILLON MAD.+ALGOD. PURO TU	SWAB IN TUBE WOOD+PURE COTTON
300250.M	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300261.M	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON
300268.B	ESCOBILLON PS+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST.WIRE+VISCOSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCO
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOS
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSE SWAB FLOW
310211.1	ESCOBILLON PS+ALGODON B/2 FLOW	PS+COTTON SWAB B/2 FLOW
300250.MY	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300211.10	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300261AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, nº 1
Pol. Ind. La Llana
08191 Rubí (Barcelona) – España

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL, CON PUNTA ABSORBENTE, PARA TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE.
INVASIVE STERILE COLLECTION SWAB, WITH ABSORBENT TIPPED, FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM
(Códigos según Anexo 1 / *Codes in Annex 1)*

Tipo: Escobillón estéril con punta absorbente para la recogida de muestras.
Type: *Absorbent tipped sterile swab for samples collection.*

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos
Intended Use*: Collection and transport of biological samples for subsequent microbiological analysis*

Código GMDN / *GMDN Code:* 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

ESCOBILLON - *Swab*

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en **Real Decreto 1591/2009.**
Directive 93/42/ECC *Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1591/2009.***

Clasificación: Clase I Estéril
Classification: Class I Sterile

INFORMACIÓN ADICIONAL
En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005 06 0475 CP Epígrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Organismo Notificado número 0318.

OTHER INFORMATION:
For the swabs, this documentation is supported by the CE Certificate number 2005 06 0475 CP Epigraph 6, according to Annexes VII section 5 and V section 3 of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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TUBO CON MEDIO DE TRANSPORTE – *Tube with transport medium*

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.
Transposición a la legislación española en **Real Decreto 1662/2000.**
Directive 98/79/EC *In vitro Diagnostic Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1662/2000.***

deltalab
DELTALAB S.L
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubí - Barcelona
T. +34 936 995 000, F. +34 936 994 512

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS/ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
300265	ESCOBILLON PS+FLOCK EN TUBO	*SWAB / TUBE PS + FLOCK*
303806	ESCOB.FLOCK ULTRA PEEL P.	*FLOCKED SWAB PS STAND.NO/BP ST.PEEL P.*
304270	VICUM 2ML ESC.FLOCK NASOFAR. 100MM	*VICUM 2ML FLOCKED SWAB NASOPH.100MM*
304271	VICUM 1ML ESC.FLOCK ESTANDARD 80MM	*VICUM 1ML FLOCKED SWAB STANDARD 80MM*
304272	VICUM 1ML ESC.FLOCK URETRAL 80MM	*VICUM 1ML FLOCKED SWAB URETRAL 80MM*
304273	VICUM 3ML ESC.FLOCK ESTANDARD 100MM	*VICUM 3ML FLOCKED SWAB STANDARD 100MM*
304274	VICUM 3ML ESC.FLOCK URETRAL 100MM	*VICUM 3ML FLOCKED SWAB URETRAL 100MM*
304275	VICUM 3ML ESC.FLOCK NASOFARINGEO 100MM	*VICUM 3ML FLOCKED SWAB NASOPH.100MM*
304276	VICUM 2ML ESC.FLOCK URETRAL 100MM	*VICUM 2ML FLOCKED SWAB URETRAL 100MM*
304277	VICUM 1ML ESC.FLOCK NASOFARINGEO 100MM	*VICUM 1ML FLOCKED SWAB NASOPH.100MM*
304278	VICUM 2ML ESC.FLOCK ESTANDARD 80MM	*VICUM 2ML FLOCKED SWAB STANDARD 80MM*
304279	VICUM 2ML ESC.FLOCK MINITIP 100MM	*VICUM 2ML FLOCKED SWAB MINITIP 100MM*
304280	CARY BLAIR 2ML ESC.FLOCK ESTANDARD 80MM	*CARY BLAIR 2ML FLOCKED SWAB STANDARD 80MM*
304281	AMIES 1ML ESC.FLOCK ESTANDARD 80MM	*AMIES 1ML FLOCKED SWAB STANDARD 80MM*
304282	AMIES 1ML ESC.FLOCK URETRAL 80MM	*AMIES 1ML FLOCKED SWAB URETRAL 80MM*
304285	AMIES 1ML ESC.FLOCK NASOFARINGEO 100MM	*AMIES 1ML FLOCKED SWAB NASOPH. 100MM*
304286	AMIES 1ML ESC.FLOCK MINITIP 100MM	*AMIES 1ML FLOCKED SWAB MINITIP 100MM*
304287	AMIES 2ML ESC.FLOCK ESTANDARD 80MM	*AMIES 2ML FLOCKED SWAB STANDARD 80MM*
304291	VIRUS 1ML ESC.FLOCK ESTANDARD 80MM	*VIRUS 1ML FLOCKED SWAB STAND. 80MM*
304292	VIRUS 1ML ESC.FLOCK URETRAL 80MM	*VIRUS 1ML FLOCKED SWAB URETRAL 80MM*
304293	VIRUS 3ML ESC.FLOCK ESTANDARD 100MM	*VIRUS 3ML FLOCKED SWAB STANDARD 100M*
304294	VIRUS 3ML ESC.FLOCK URETRAL 100MM	*VIRUS 3ML FLOCKED SWAB URETRAL 100MM*
304295	VIRUS 3ML ESC.FLOCK NASOFARINGEO 100MM	*VIRUS 3ML FLOCK.SWAB NASOPH.100MM*
304297	VIRUS 1ML ESC.FLOCK NASOFARINGEO 100MM	*VIRUS 1ML FLOCK.SWAB NASOPH.100MM*
304296	VIRUS 2ML ESC.FLOCK NASOFARINGEO 2X100MM	*VIRUS 2ML FLOCK.SWAB NASOPH. 100MM*
304298	VIRUS 2ML ESC.FLOCK NASOF + ST. 100/80MM	*VIRUS 2ML FLOCK. SWAB NASOPH. + ST. 100/80MM*

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REF	DESCRIPCIÓN	*DESCRIPTION*
304288	AMIES 1ML 3 ESC.FLOCK MRSA	*AMIES 1ML 3 FLOCKED SWABS MRSA*
304212	LIM BROTH 2ML ESC.FLOCK ESTANDARD 80MM	*LIM BROTH 2ML FLOCKED SWAB STANDARD 80MM*

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

CONTENEDORES PARA MUESTRAS NO ESTÉRILES
GENERAL SPECIMEN CONTAINER NON-STERILE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de cualquier tipo de muestra para diagnóstico (por ejemplo, orina, heces, esputo, mucosa, tejido) para análisis y/u otra investigación.
Intended Use: *Collection and preservation and/or transport, of any type of diagnostic specimen (e.g. urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation.*

Código GMDN / *GMDN Code:* 47775

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro". Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive. Transposition to Spanish legislation in Real Decreto 1662/2000.*

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
202840	FRASCO DE SEGURIDAD 20ML	*SECURITY CONTAINER 20ML*
202841	FRASCO DE SEGURIDAD 40ML	*SECURITY CONTAINER 40ML*
202842	FRASCO DE SEGURIDAD 60ML	*SECURITY CONTAINER 60ML*
202843	FRASCO DE SEGURIDAD 90ML (Ø48-h75)	*SECURITY CONTAINER 90ML (Ø48-h75)*
202844	FRASCO DE SEGURIDAD 120ML	*SECURITY CONTAINER 120ML*
202845	FRASCO DE SEGURIDAD 250ML	*SECURITY CONTAINER 250ML*
202846	FRASCO DE SEGURIDAD 500ML	*SECURITY CONTAINER 500ML*
202847	FRASCO DE SEGURIDAD 1000ML	*SECURITY CONTAINER 1000ML*
202848	FRASCO DE SEGURIDAD 90ML(Ø53-h68)	*SECURITY CONTAINER 90ML(Ø53-h68)*
300100	TUBO 17 ML PS 16X150 MM	*PS TUBE 16X150*
300101	TUBO PS 8ML 16X75MM GRADUADO C/BORDE	*PS TUBE 8ML 16X75MM GRADUATED WITH RIM*
300300	TUBO 4 ML PS 11X70 MM	*TUBE 11X70 PS*
300400	TUBO 6 ML PS 12X88 MM GRADUADO	*TUBE 12X88 PS GRADUATED*
300500	TUBO 3 ML PS 11X55 MM	*TUBE 11X55 PS*
300700	TUBO 13X75 PS	*TUBE 13X75 PS*
300702	TUBO 13X75 PS TAPADO	*TUBE 13X75 PS CAPPED*
300704	TUBO 13X75 PS TAPADO Y ETIQ	*TUBE 13X75 PS CAPPED&LABELLED*
300705	TUBO 10 ML PS 16X100 MM	*TUBE 16X100 PS*
300800	TUBO 5ML PS 12X75 MM GRADUADO	*TUBE 5ML PS 12X75MM GRADUATED*
300802	TUBO 12X75 PS + TAPON 305802	*PS TUBE 12X75 + CAP 305802*
300804	TUBO 12X75 PS TAPADO Y ETIQ	*TUBE 12X75 PS CAPPED LABELLED*
300900	TUBO 10ML PS 16X95MM GRADUADO	*TUBE 10ML PS 16X95MM GRADUATED*
300903	TUBO 16x95 PS TAPADO	*TUBE 16x95 POLYSTYRENE CAPPED*
300904	TUBO 10 ML PS 16X95 MM TAPADO ETIQUETADO	*TUBE 16X95 PS CAPPED LABELLED*
300907	TUBO 16X100 PS TAPADO	*TUBE 16X100 PS CAPPED*
300908	TUBO 16X100 PS TAPADO Y ETIQ	*TUBE 16X100 PS CAPPED LABELLED*
300911	TUBO 16X100 PS TAPADO C/308101	*TUBE 16x100 PS CAPPED W/308101*
300912	TUBO 16X95 PS TAPADO 305002	*16X95 TUBE PS CAPPED 305002*

REF	DESCRIPCIÓN	*DESCRIPTION*
300913	TUBO 16X95 PS TAPADO	*TUBE 16X95 PS CAPPED*
300914	TUBO 16x95 TAPADO 305002	*16x95 TUBE CAPPED 305002*
301200	TUBO CONICO 16X102 PS	*CONICAL TUBE 16X102 PS*
301201	TUBO CONICO 12ML PS 16X100 MM	*CONICAL TUBE 16X100 PS*
301202	TUBO CONICO 16X102 PS	*CONICAL TUBE 16X102 PS*
301205	TUBO CONICO 301200 TAP/305502	*PS TUBE 12ML CONICAL CAPPED*
301206	TUBO CONICO 16X102+TAP.305502	*PS CON. TUBE 16X102 + CAP305502*
301207	TUBO CONICO 16x102 PS TAPADO	*CONICAL TUBE 16x102 PS CAPPED*
301212	TUBO CONICO 12 ML PS 17X105 MM	*CONICAL TUBE 17X105 PS*
301213	TUBO CÓNICO 12ML PS 16X105MM	*CONICAL TUBE 12ML PS 16X105MM*
301403	TUBO 12ML PS 15X102 MM TAPADO FALDON	*TUBE 12ML PS CAPPED*
301700	TUBO 7 ML PS 13X100 MM	*TUBE 13X100 PS*
309201	FRASCO 30ML PS ETIQUETADO	*30ML UNIVERSAL LABELLED PS*
309202	FRASCO 30ML PS	*30ML CONTAINER PS*
309206	FRASCO 30ML PS TAPON ROJO	*30ML PS CONTAINER RED CAP*
309207	FRASCO 30ML PS TAP.CU SEPARADA	*PS 30ML CONTAINER SEPARATED CAP*
309222	FRASCO 30ML PS B/U	*30ML CONTAINER I/W PS*
309402	FRASCO 40ML PS	*PS 40ML CONTAINER*
309501	FRASCO 60ML PS ETIQUETADO	*PS 60 ML CONTAINER PRINTED LBL*
309502	FRASCO 60ML PS	*60ML CONTAINER PS*
309505	FRASCO 60ML PS T/AZUL	*CONTAINER PS 60ML BLUE CAP*
309552	FRASCO 60ML PS ESPATULA	*60ML CONTAINER WITH SPOON PS*
400400	TUBO 6 ML PP 12X88 MM GRADUADO	*TUBE 12X88 PP GRADUATED*
400500	TUBO 3 ML PP 11X55 MM	*TUBE 11X55 PP*
400700	TUBO 5 ML PP 13X75 MM	*TUBE 13X75 PP*
400705	TUBO 10 ML PP 16X100 MM	*TUBE 16X100 PP*
400800	TUBO 5ML PP 12X75 MM GRADUADO	*TUBE 5ML PP 12X75MM GRADUATED*
400806	TUBO 75X12 PP TAPADO T/ROJO	*TUBE 12x75 PP CAPPED 305806*
400900	TUBO 16X95 PP	*TUBE 16X95 PP*
400908	TUBO 16x95 TAPADO 305007	*16X95 PP TUBE CAPPED 305007*
401100	TUBO 5 ML PP 15X50 MM	*TUBE 15X50 PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
401200	TUBO CONICO 12 ML PP 16X102 MM	*CONICAL TUBE 16X102 PP*
401201	TUBO CONICO 12 ML PP 16X100 MM	*CONICAL TUBE 16X100 PP*
401202	TUBO CONICO 16x102+TAPON 16MM	*CONICAL TUBE 16x102 + CAP 16MM*
401204	TUBO CÓNICO 12ML PP 16X100 MM	*CONICAL TUBE 12ML PP 16X100MM*
401307	TUBO CONICO 16X102 PP TAPADO	*CONICAL TUBE 16x102 PP CAPPED*
401403	TUBO 12ML PP 15X102 MM TAPADO FALDON	*PP 12 ML TUBE CAPPED*
401700	TUBO 7 ML PP 13X100 MM	*PP TUBE 13X100*
408702	FRASCO 150 ML PP AL VACÍO	*CUP F/VACUUM COLLECTION 150ml*
408726	FRASCO 150 ML PP B/U AL VACÍO	*CUP F/VACUUM COLLEC.150ml I/B*
409201	FRASCO 30ML PP ETIQUETADO	*30ML CONTAINER LABEL PP*
409202	FRASCO 30ML PP	*30ML CONTAINER PP*
409222	FRASCO 30ML PP BOLSA UNITARIA	*30ML CONTAINER I/W PP*
409402	FRASCO 40ML PP GRADUADO	*40ML CONTAINER PP GRADUATED*
409426	FRASCO 40ML PP B/U GRADUADO	*40ML CONTAINER I/W PP*
409501	FRASCO 60ML PP ETIQUETADO	*60ML CONTAINER LABELLED PP*
409502	FRASCO 60ML PP	*60ML CONTAINER PP*
409507	FRASCO 60ML PP ROSCADO T/VERDE	*60ML SCREW CAP CONT PP C/GREEN*
409511	FRASCO 60ML PP ETIQUETADO T/AZUL	*60ML BLUE CONTAINER LABEL PP*
409552	FRASCO 60ML PP C/ESPATULA	*60ML CONTAINER W/SPOON*
409556	FRASCO 60 ML. B/UNIT. CUCHARA	*60 ML PP CONTAINER WITH SPOON UNIT BAG*
409602	FRASCO 30ML PP C/CUCHARA	*30ML CONTAINER WITH SPOON PP*
409662	FRASCO 30ML.T/AZUL CUC S/ROSC	*SCREW CAP CONT.30ml PP*
409701	FRASCO 150ML PP ETIQUETADO	*150ML CONTAINER LABELLED PP*
409702	FRASCO 150ML PP	*150ML CONTAINER PP*
409703	FRASCO 150ML PP SIN ROSCAR	*150ML CONT SEPARATED CAP PP*
409707	FRASCO 150ML PP T/VERDE	*PP 150 ML CONTAINER GREEN CAP*
409711	FRASCO 150ML AZUL ETIQUETADO	*150ML BLUE CONTAINER LABEL PP*
409752	FRASCO 150ML PP C/CUCHARA	*150ML CONTAINER WITH SPOON PP*
409756	FRASCO 150ML B/U ESPATULA PP	*150ML CONTAINER I/W SPOON PP*
409802	FRASCO 50ML PP	*50ML CONTAINER PP*
409826	FRASCO 50ML PP B/U	*50ML CONTAINER I/W PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
409852	FRASCO 50ML PP CON ESPATULA	*50ML CONTAINER WITH SPOON PP*
409902	FRASCO 200ML PP	*200ML CONTAINER PP*
409905	FRASCO 200ML PP AZUL TRANS. ETI	*CONTAINER 200 ML PP BLUE-PLAIN LBL*
409915	FRASCO 200ML PP AZUL TRANS S/E	*CONTAINER 200 ML PP BLUE*
409926	FRASCO 200ML PP B/U	*200ML CONTAINER PP I/W*
410046	FRASCO 50 ML PP T/PRECINTO	*TAMPER EVIDENT CONT.50ml H80mm*
410047	FRASCO T/BISAGRA 50ml H=80mm	*HINGED LID CONT.50ml H=80mm*
410056	FRASCO PRECINTO 50ml H80mm B/U	*HINGED LID CONT.50ml H80mm I/B*
419802	FRASCO 50ML PP T/PRECINTO	*50ML CONT SEALED CAP PP*
419805	FRASCO 50ML PP T/PRECI AZUL	*PP 50 ML CONT. SEALED CAP BLUE*
419825	FRASCO 50ML PP T/PREC.AZUL B/U	*50ML CONT SEAL.BLUE CAP I/W PP*
419826	FRASCO 50ML PP T/PRECINTO B/U	*50ML CONT SEALED CAP I/W PP*
429900	TUBO CONICO 50 ML PP TAPADO	*50ML CONICAL TUBE PP*
429901	TUBO CONICO 50ML PP FALDON TAPADO	*50ML CONICAL TUBE SKIRT PP*
429903	TUBO 50ML PP CON.FALDON S/TAP	*50ML CON.TUBE SKIRTE PP NO CAP*
429910	TUBO CONICO 15ML PP TAPADO	*15ML CONICAL TUBE PP*
444602801	FRASCO DE SEG. 60ML T/AZUL	*CHILD PROOF CONT 60ML BLUE LID*
444602802	ANTI-CHILD. SIN TAPON	*CHILD PROOF CONT.60ML NO CAP*
444602901	FRASCO SEGURIDAD 60ML T/AZUL	*CHILDPROOF CONT 60ML BLUE LID*
444602903	ANTI-CHILD BLANCO T/BLANCO 60	*CHILD PROOF WHITE CONTAINER 60*
444603202	FRASCO DE SEG. 30ML T/BLAN PRECINTO	*SECURITY CONT. 30ML WHITE CAP*
444603204	F.SEGURIDAD BLANCO 30ML T/BLANCO	*CHILDPROOF WH.CONT 30ML B/CAP*
444603300	FRASCO SEGURIDAD 60ML T/BLANCO	*CHILDPROOF CONT 60ML WHITE LID*
444603305	ANTI-CHILD.AZUL TAPON BLANCO	*CHILD PROOF BLUE CONT.WHITE CAP*
444603306	ANTI-CHILD. VERDE TAPON BLANCO	*CHILD PROOF GREEN CONT.WHITE CAP*
444603308	ANTI-CHILD.ROJO TAPON BLANCO	*CHILD PROOF RED CONT.WHITE CAP*
444603402	F. SEGURIDAD 125ML T/BLANCO	*CHILDPROOF CONT 125ML WHITE LID*
202845N	TARRO HISTOLOGIA 250ML NEGRO	*HISTOLOGY CONTAINER 250ML BLACK*
202846/T	FRASCO DE SEGURIDAD 500ML TAPADO	*SECURITY CONTAINER 500ML CAPPED*
202847/T	FRASCO DE SEGURIDAD 1000ML TAPADO	*SECURITY CONTAINER 1000ML CAPPED*

REF	DESCRIPCIÓN	*DESCRIPTION*
300500.8	TUBO 11X55 PS	*TUBE 11X55 PS*
300800.1	TUBO 5 ML PS 12X75 MM SIN ENRASES	*TUBE 12X75 PS*
300800.2	TUBO 12X75 PS REFORZADO	*TUBE 12X75 PS*
300900M	TUBO 16X95 PS GRAD.CAJA 5X100	*TUBE 16X95 PS GRAD.CASE 5X100*
309202.4	FRASCO 30ML PS	*PS 30 ML. UNIVERSAL PLAIN LBL*
309202.NR	FRASCO 30ML PS	*30ml CONTAINER PS NO SCREW*
309202V	FRASCO 30ML PS TAPÓN VERDE	*30ML CONTAINER PS GREEN CAP*
309202.WO	FRASCO 30ML PS SIN TAPÓN	*CONT.30ML PS NO CAP*
309222.1	FRASCO 30ML PS B/U ETIQUETADO	*CONTAINER 30 ML. UNIT BAG LABEL*
309501BE	FRASCO 60ML PS B/50 CÓD. BARRAS	*60ML PS CONTAINER B/50 BAR COD*
309502.10	FP-60 S/ROSCAR C/600 T/ROJO	*CONT.60ML C/600 RED CAP*
309502.6	FRASCO 60 ML. PS ETIQUETA BLANC	*PS 60 ML. CONTAINER PLAIN LABEL*
309602E	FRASCO 30ML PS CON ESPATULA ETIQUETADO	*30ML CONTAINER WITH SPOON PS*
309622.1	FCO.30 CUCH. ETIQ. ESP. B/UNIT.	*PS 30ML SPOON+LABEL+UNIT BAG CONT.*
400004.1	FRASCO 125ML PP 57X73	*125ML CONTAINER PP*
400500.B	TUBO 11x55 PP B/400	*TUBE 11x55 PP B/400*
400706E	TUBO 10ML C/A.BORICO TAP.ETIQ.B/U	*100ML TUBE W/BORIC A. CAP.LAB. I/W*
400800.1	TUBO 5 ML PP 12X75 MM SIN ENRASES	*TUBE 12X75 WITHOUT RINGS PP*
400906BOR	TUBO 16X100 TAP- 308106 AC. BOR	*TUBE 16X100 PP CAP ACID BORIC*
400906MD	TUBO 16x100 PP TAPADO 308106	*16x100 TUBE PP CAPPED 308106*
409201.S	FRASCO 30ML PP ETIQUETADO	*30ML CONTAINER LABEL PP*
409201.SE	FRASCO 30ML PP ETIQUETADO B100	*30ML CONTAINER LABEL PP B/100*
409202.8	FRASCO 30 ML TAPADO TAPON AZUL	*30ML CONTAINER PP BLUE CAP*
409202.WO	FRASCO 30ML PP SIN TAPÓN	*CONT. 30ML PP NO CAP*
409203.2	FRASCO 30ML PP T/BLAN ENV. SEP	*PP 30 ML+ WHITE CAP SEPARAT.C/1800*
409203.2A	FR.30ML PP T/BL.ENV.SEP.C/ANO	*PP 30ML WHITE CAP SEP.PLAIN BO*
409502.2B	FR.60ML ETIQ.T/ROJO 10X50	*CONT.60ML LABEL RED C.10X50*
409502.2C	FR. 60ML PP ETIQ.T/ROJO 16X50	*60ML CONT. PP LABEL RED CAP 16X50*
409502.4	FRASCO 60ML S/ROSCAR 38X65 PP	*60ML CONT. UNCAPPED 38X65MM PP*
409502.4Y	FRASCO 60ml S/ROSCAR PP T/AMA	*60ml CONT.UNCAPPED PP YEL/LID*
409502G	FRASCO 60ML GRADUADO	*60ML CONTAINER GRADUATED PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
409502G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	*CONT.60 GRAD.UNCAPPED SEP.CAP*
409507G	FRASCO 60ml PP GRAD.T/VERDE	*60ml CONT.PP GRAD.GREEN CAP*
409511.4	FR.60ML AZUL CLARO S/ETIQUETA	*60ML LIGHT BLUE CONTAINER*
409511.5	FR.60ML AZUL TRANSL. ETIQ. BLANC	*60ML CONTAINER TRANS.BLUE LBL*
409552.Y	FRASCO 60ml PP C/ESPÁTULA T/AM	*60ml CONTAINER W/SPOON YEL/LID*
409552G	FRASCO 60ML PP GRADUADO C/ESPA	*60ML CONTAINER W/SPOON GRADUAT*
409552.TA	FRASCO 60ML PP C/ESPATULA T.AZUL	*60ML CONTAINER PP W/SPOON BLUE CAP*
409702.3	FRASCO 150ml PP TAPÓN BLANCO	*PP CONTAINER 150ml WHITE CAP*
409702.P	FRASCO 150ML PP ROSCADO	*150ML PP CUPPED CONTAINER*
409702.PB	FRASCO 150ML PP ROSCADO T.BLA	*150ML PP CUPPED CONT.WHITE C.*
409703.5	FRASCO 150 ML. T/AZUL S/ROSCAR	*150ML CONT SEPARATED BLUE CAP*
409703WC	FRASCO 150ML PP SIN ROSCAR T/BLANCO	*150ML PP CONT.SEPAR.CAP WHITE*
409711.4	FR.150ML AZUL CLARO S/ETIQUETA	*150ML LIGHT BLUE CONTAINER*
409711.5	FR.150ML AZUL TRANS. ETIQ. BLANC	*150ML CONTAINER BLUE TRANSL.LB*
409805.6	FRASCO 50ML PP T/ROJO SEPARADO	*50ML PP CONTAINER SEP. RED CAP*
410046.5	FRASCO T/PREC.50ml H80mm C/500	*HINGED LID CONT.50ml H80 C/500*
410046A.5	FRASCO T/PREC.50ml 500UD AZUL	*HINGED LID CONT.500U BLUE*
410046R.5	FRASCO T/PREC.50ml 500UD ROSA	*HINGED LID CONT.500U PINK*
420900E	TUBO 12ML PP S/TAPON C/FALDON	*PP 12ML TUBE W/SKIRT W/OUT CAP*
429900.25	TUBO CONICO 50ml PP B/25	*50ml CONICAL TUBE PP B/25*
429900SP	TUBO 50ML PP CONICO SIN ROSCAR	*50ML CONICAL TUBE PP SEP.CAP*
429901.25	TUBO CON.50ml PP C/FALDON B/2	*50ml CONICAL TUBE W/SKIRT B/25*
429910SP	TUBO 15ml PP CONICO SIN ROSCAR	*15ml CONICAL TUBE PP SEP.CAP*
429927S/E	TUBO CONICO 50ML C/FALDON B/U	*50ML CONICAL TUBE SKIRT I/W PP*
44462903M	ANTI-CHILD BLANCO T/BLANCO 60	*CHILDPROOF WHIE CONT.60ML WC*
309202.O	FRASCO 30ML PS ST. EO	*CONTAINER 30ML PS ST.EO*
429930	TUBO 50ML PP CONICO IMPRESO B/25	*50ML TUBE PP CONICAL PRINT 25/B*
429940	TUBO 15 ML PP CONICO IMPRESO GRANEL	*15ML TUBE PP CONICAL PRINTED IN BULK*
429945	TUBO 15 ML PP CONICO IMPRESO B/25	*15ML TUBE PP CONICAL PRINT 25/B*

REF	DESCRIPCIÓN	*DESCRIPTION*
429950	TUBO 50 ML PP CONICO IMPRESO C/F B/25	*50ML TUBE PP CONICAL PRINT SKIRTED 25/B*
300500MI	TUBO 11X55 PS	*TUBE 11X55 PS*
175723	TUBO 5ML PS 13X75 TAPADO ROJO	*TUBE 5ML PS 13X75 CAPPED RED*
175724	TUBO 10ML PS 16X95 TAPADO ROJO	*10ML TUBE PS 16X95 CAPPED RED*
400903	TUBO 10ML PP 16X95 TAPADO ROJO	*10ML TUBE PP 16X95 CAPPED RED*
661035	TUBO 10ML PS 16X95 TAPADO NATURAL	*10ML TUBE PS 16X95 CAPPED NATURAL*
408702C	FRASCO VACÍO 120ml LOTE IMPRESO	*VACUUM CONT.120ML CML*
408726.A	FRASCO P/VACÍO 120ml B/I C/AN.	*CUP F/VACUUM 120ml I/B PLAIN/C*
400805	TUBO 75X12 PP TAPADO T/AZUL	*TUBE 75X12 PP CAPPED C/BLUE*
202844/T	FRASCO DE SEGURIDAD 120ML TAPADO	*SECURITY CONTAINER 120ML CAPPED*
409557	FRASCO 60ML PP C/ESPATULA T/VERDE	*CONTAINER 60ML PP W/SPOON GREEN CAP*
419802.T	FRASCO 50ML PP T/PREC. DESTAPADO	*CONTAINER 50ML PP C/TAMPER EVID. UNCOVERED*
409502.4B	FRASCO 60ML PP T/AZUL NO TAPADO	*60ML CONTAINER PP BLUE CAP UNCOVERED*
409702B	FRASCO 150ML PP B/50	*150ML CONTAINER PP B/50*
309205	FRASCO 30ML PS T/AZUL ETIQ.	*30ML CONTAINER PS BLUE CAP LABEL*
429906SP	TUBO 50ML PP CONICO T/ROJO SIN ROSCAR	*50ML CONICAL TUBE PP SEP.CAP RED*
429901SP	TUBO CONICO 50ML PP FALDON SIN ROSCAR	*TUBE 50ML PP SKIRTED SEP. CAP*
175725	TUBO 3ML PS 11X55 TAPADO ROJO	*TUBE 3ML PS 11X55 CAPPED RED*
409511.4TA	FRASCO 60ML PP C/CUCHARA T/AZUL	*CONTAINER 60ML PP W/SPOON BLUE CAP*
202842A	FRASCO SEGURIDAD 60ML T/AZUL	*CONTAINER 60ML BLUE CAP*
202844A	FRASCO DE SEGURIDAD 120ML T/AZUL	*SECURITY CONTAINER 120ML BLUE CAP*
409512	FRASCO 60ML PP T/ROJO C/GRIS	*CONT. 60ML PP RED C. GREY B.*
301201CA	TUBO CONICO 12ML PS 16X100 MM	*CONICAL TUBE 16X100 PS*

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – CITRATO TAMPONADO
BLOOD CONTAINERS – SODIUM CITRATE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (p.ej. para estudios de coagulación del plasma)
Intended Use: *Collection and preservation and/or transport, of blood for analysis and/or other (e.g. for plasma coagulation studies)*

Código GMDN / *GMDN Code:* 58139

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro". Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive. Transposition to Spanish legislation in Real Decreto 1662/2000.*

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
601102	TUBO CITRATO PP 4 ML	CITRATE TUBE 4ML PP
601103	TUBO CITRATO PP 2,5ML	CITRATE TUBE 2.5ML PP
601203	TUBO CITRAT TAMP 3,2% PP 2,5ML	CITRATE TUBE 3.2% 2.5ML PP
621101	TUBO CITRATO 1ML PERFORABLE	CITRATE TUBE 1ML PIERCEABLE
621102	TUBO CITRATO 2ML PERFORABLE	CITRATE TUBE 1ML PIERCEABLE
601103.2	TUBO CITRATO 2.5ML RETRACTIL	CITRATE TUBE 2.5ML WRAPPEDRACK
601203.1	TUBO CITRATO 3.2% 2.5ML GRANEL	CITRATE TUBE 3.2% 2.5ML BULK

deltalab

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – K3EDTA
BLOOD CONTAINERS – K3EDTA
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, hematología de sangre como conteo sanguíneo completo (SCS), y determinación cuantitativa de drogas.
Intended Use: *Collection and preservation and/or transport of blood for analysis and/or other investigation (e.g.whole blood hematology such as complete blood count (CBC) and quantitative drug assay determinations.*

Código GMDN / GMDN *Code:* 58143

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro".
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive.*
Transposition to Spanish legislation in Real Decreto 1662/2000.

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
601603	TUBO EDTA TRIPOTASICO 2,5ML PP 13X75MM	EDTA TUBE TRI-K R/BOT 2.5ML PP
601612	TUBO EDTA TRI-K PP 4ML	EDTA TUBE TRI-K 4ML PP
601613	TUBO EDTA TRI-K PP 2,5ML	EDTA TUBE TRI-K 2.5ML PP
601702	TUBO EDTA TRI-K PP 4ML	EDTA TUBE TRI-K 4ML PP
611604	TUBO EDTA TRI-K 3ML PP 13X80 T/GOMA PERF.	EDTA TRI-K TUBE 3ML PP 13X80 RUBBER CAP PERF.
621610	TUBO EDTA TRI.1ML PP 12X55MM T/PRE PERF.	EDTA TUBE TRI-K 1ML PP 12X55MM C/PRE-PERF.
621611	TUBO EDTA TRI-K 2ML 16X55 FALDON T/PRE-PERF.	EDTA TUBE TRI-K 2ML 16X55 SKIRTED C/PRE-PERF.
621613	TUBO EDTA TRI 2,5ML PP 13X80MM T/PERFOR.	EDTA TUBE TRI-K 2.5ML PP 13X80MM T/PRE-PERF.
601603.2	TUBO EDTA TRI-K 2.5ML RETRACTILADO	EDTA TRI-K TUBE 2.5ML WRAP/RAC
601702.2	TUBO EDTA TRI-K 4ML RETRACTILADO	EDTA TRI-K TUBE 4ML WRAPP/RACK
611603.1	TUBO EDTA TRI-K PULV. 3ML 13X75 T/PERFO	EDTA TUBE PUL.K3 3ML PIERC.CAP

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – SEROTUB
BLOOD CONTAINERS – SEROTUBE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, determinación química del suero sanguíneo).
Intended Use: *Collection and preservation and/or transport, of blood for analysis and/or other investigation (e.g. blood serum chemistry determinations)*

Código GMDN / GMDN *Code:* 58138

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro".
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive.*
Transposition to Spanish legislation in Real Decreto 1662/2000.

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
600300	TUBO SUERO PP 9ML GRANULOS	SEROTUBE W/GRANULES PP 9ML
600400	TUBO SUERO PP 4ML GRANULOS	SEROTUBE W/GRANULES PP 4ML
600602	SEROTUB GLUCOSA PP 4ML	SERUM GLUCOSE 4ML GRANULES PP
600610	SEROTUB GLUCOSA PP 10ML	PP SERUM GLUCOSE 10ML GRANULES
600800	TUBO SUERO PP 9ML GEL	SERUM TUBE W/GEL 9ML PP
600801	TUBO SUERO PP 4ML GEL	SERUM TUBE W/GEL 4ML PP
620200	TUBO SUERO 2ML PERF GRANULOS	SERUM TUBE 2ML PIER W/GRANULES
620300	TUBO SUERO 10ML PERF GRANULOS	SERUM TUBE 10ML PIER W/GRANULE
620400	TUBO SUERO 4ML PERF GRANULOS	SERUM TUBE 4ML PIER W/GRANULES
620800	TUBO SUERO 10ML PERF GEL	SERUM TUBE 10ML PIERCEABLE GEL

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder:

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope:

Design, development, manufacture, distribution, servicing of:
-Instruments and reagents for clinical diagnostic.
-Instruments and reagents for agro-alimentary analysis.
Distribution and service of reagents and instruments for veterinary diagnosis.

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

Validity:

The certificate is valid from 2019-12-19 until 2022-12-18.
First certification 1996

2019-12-20

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/02	BIOSYSTEMS S.A. Pol. Ind. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labeling and assembly of reagent. Storage, and shipping of: - Instruments and reagents for diagnosis and reagents for clinical diagnosis.- Instruments and reagents for agri-food analysis.- Instruments and reagents for veterinary diagnosis.

2019-12-20

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture, distribution and servicing of instruments and reagents for clinical diagnostic
(see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-01-08
Certificate Registration No.:	SX 60145545 0001
An audit was performed. Report No.:	28300434 004
This Certificate is valid until:	2022-12-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2020-01-08

D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.: SX 60145545 0001
Report No.: 28300434 004

Organization:
BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope:

Site included:

Polígono Industrial Can Tapioles
Naves 7, 12 y 13
08110 Montcada i Reixac
Spain

Activity: Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-01-08

D. Swiatko

BioSystems
REAGENTS & INSTRUMENTS

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard
Adenosine Deaminase (ADA) Standard
Albumin (Microalbuminuria) Standard
Anti-Streptolysin O (ASO) Standard
Antithrombin III Standard
Apolipoprotein A-I Standard
Apolipoprotein B Standard
b2-Microglobulin Standard
Bilirubin Standard
Biochemistry Calibrator
Biochemistry Calibrator (Human)
Cholesterol HDL/LDL Calibrator
CRP/CRP-hs Standard
Ferritin Standard
Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Prealbumin Standard
Protein Calibrators
Protein (urine) Standard
Rheumatoid Factors (RF) Standard

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct
a-Amylase-Pancreatic
Adenosine Deaminase (ADA)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
Aspartate Aminotransferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total)
Calcium-Arsenazo
Cholesterol
Cholesterol HDL direct
Cholesterol LDL direct
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
g-Glutamyltransferase (g-GT)
Glucose
Iron Ferrozine
Lactate dehydrogenase (LDH)
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Triglycerides
Urea/BUN UV
Uric acid

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)
Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)
Anti-Centromere B Antibodies (CENP-B)
Anti-Citrullinated Protein Antibodies (ACPA)
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)
Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:
AUTOIMMUNITY – INSTRUMENTS:

iPRO

RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide
Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon
TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Certificate Holder:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **65-467-1304**

Effective Date: **2019-08-26**

Expiry Date: **2021-10-23**

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Overall Scope Statement:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 65-467-1304

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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CERTIFICATE

No. QS6 044751 0135 Rev. 01

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106, Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 54-459-5743

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
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SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD ISO 9001

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH2005501**

Effective Date: **2020-08-12**

Expiry Date: **2023-06-30**

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor , Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

Declaration of Conformity CE

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: **Auto Hematology Analyzer**
Model: **BC-3600**
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2011-01-14
Place, Date of Issue: Shenzhen, 2011-01-14

Signature: .....
Name of Authorized Signatory: Mr. Yang Long
Position Held in Company: Management Representative

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-20s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-30s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-20s、BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2011	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and

Declaration of Conformity V 1.0

	laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors GmbH
Leibnizstraße 4
93055 Regensburg
Germany

has established and applies
a Quality Management System for

Design, development and production of
opto semiconductor wafer,
opto electronic components and displays.

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/11 TMS**.

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

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Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors (Malaysia) SDN. BHD

Bayan Lepas Free Industrial Zone Phase 1
11900 Bayan Lepas, Penang
Malaysia

has established and applies
a Quality Management System for

Design, development and production of
opto semiconductor wafer,
opto electronic components and displays.

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/12 TMS**.

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

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Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors, Inc.
Kifer Road 1150
Sunnyvale, California, CA 94086
USA

has established and applies
a Quality Management System for

Sales, marketing, customer service and logistics.

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/14 TMS**.

Product Compliance Management
Munich, 2016-11-25

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

M/S/01-07/2014

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors (China) Co. Ltd.

No. 57, XiQin Rd
Wuxi New District, Jiangsu, P.R. China
Post Code: 214028

Organisation code: 05524191-X

has established and applies
a Quality Management System for

Production of
Opto Semiconductor components and displays.

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/18 TMS**.

Information about this certificate can be inquired at the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

M/S/01-07/2014

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EU Declaration of Conformity

OSRAM

Document number:	2016 / 9C1-3364256-EN-00
Manufacturer or representative:	OSRAM GmbH
Address:	Marcel-Breuer-Str. 6 80807 München Germany
Brand name or trade mark:	OSRAM
Product type:	Lamp controlgear
Product designation:	QUICKTRONIC
	☒ See attached list

The designated product(s) is (are) in conformity with the relevant Union harmonisation legislation:

☒	**Low Voltage Directive:**	**2006/95/EC: Directive of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (until 19.04.2016)** **2014/35/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Official Journal of the EU L96, 29/03/2014, p. 357-374 (from 20.4.2016)**
☒	**EMC Directive:**	**2004/108/EC: Directive of the European Parliament and of the Council of 15 September 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (until 19.04.2016)** **2014/30/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Official Journal of the EU L96, 29/03/2014, p. 79-106 (from 20.4.2016)**
☒	**2009/125/EC** and amendments	**Directive of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products**
☐	**244/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps**
☒	**245/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps, and repealing Directive 2000/55/EC of the European Parliament and of the Council**
☐	**1194/2012** and amendments	**Commission Regulation (EU) No 1194/2012 of 12 December 2012 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for directional lamps, light emitting diode lamps and related equipment**
☒	**2011/65/EU** and amendments	**Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment; Official Journal of the EU L174, 1/07/2011, p. 88-110**
☐	**1999/5/EC** and amendments	**Directive of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity**

Last two digits of the year in which the CE marking was affixed: 16

Place and date of signatures: München, 20.04.2016

Signatures:	LS QM QMP Veser Alwin	QM&EHS LAB 1 Schemmel Bernhard
	Quality Management	Quality Assurance
Names:	Mr. Alwin Veser	Mr. Bernhard Schemmel

Customer service contact: OSRAM GmbH, Steinerne Furt 62, 86167 Augsburg, Deutschland

This declaration of conformity is issued under the sole responsibility of the manufacturer or representative. It certifies compliance with the indicated Directives, but implies no warranty of properties.

1051 04/2016

EU Declaration of Conformity
Annex

Document number: 2016 / 9C1-3364256-EN-00

The conformity of the designated product(s) with the provisions of the European **Low Voltage Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☒	**EN 61347-1:** 2008 + A1:2011 + A2:2013	Lamp controlgear — Part 1: General and safety requirements
☒	**EN 61347-2-3:** 2011 + Corr. 2011	Lamp controlgear — Part 2-3: Particular requirements for a. c. and/or d. c. supplied electronic ballasts for fluorescent lamps

The conformity of the designated product(s) with the provisions of the European **EMC Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☒	**EN 55015:** 2013	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment
☒	**EN 61000-3-2:** 2014	Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
☒	**EN 61000-3-3:** 2013	Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection
☒	**EN 61547:** 2009	Equipment for general lighting purposes — EMC immunity requirements

The conformity of the designated product(s) with the provisions of the European Directive **2009/125/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☒	**EN 62442-1:** 2011	Energy performance of lamp controlgear - Part 1: Controlgear for fluorescent lamps - Method of measurement to determine the total input power of controlgear circuits and the efficiency of the controlgear

The conformity of the designated product(s) with the provisions of the European Directive **2011/65/EU** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 50581:** 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
☒	**internal report**	

EU Declaration of Conformity
Attached list

Document number: 2016 / 9C1-3364256-EN-00

QTi 1x14/24/21/39 GII

QTi 1x28/54/35/49 GII

QTi 2x14/24/21/39 GII

QTi 2x28/54/35/49 GII

QTi 1x/35/49/80 GII

QTi 2x35/49/80 GII

QTP-OPTIMAL 1x18-40

QTP-OPTIMAL 2x18-40

QTP-OPTIMAL 1x54-58

QTP-OPTIMAL 2x54-58

QTP5 1x49

QTP5 1x80

QTP5 1x14-35

QTP5 2x14-35

QTP5 2x49

QTP5 3x14, 4x14

QTP-FC 1x55

QTP-M 1x26-42

QTP-M 2x26-32

QT-M 2x26-42/220-240 S

QT-FQ 2x80

QTP-DL 1x18-24

QTP-DL 1x36-40

QTP-DL 2x18-24

QTP-DL 2x36-40

QTP-DL 1x55 GII

QTP-DL 2x55 GII

QTP-D/E 1x10-13

QTP-D/E 2x10-13

QTP-T/E 1x26-42, 2x26

QTP-T/E 1x18, 2x18

QT-FIT 5/8 1x18-39

QT-FIT 5/8 2x18-39

QT-FIT 5/8 1x54-58

QT-FIT 5/8 2x54-58

1051 04/2016

Declaration of Conformity
Attached list

Document number: 2016 / 9C1-3364256-EN-00

QT-FIT5 1x14-35

QT-FIT5 2x14-35

QT-FIT5 3x14, 4x14

QT-FIT5 1x49

QT-FIT5 2x49

QT-FIT8 1x18

QT-FIT8 1x36

QT-FIT8 1x58-70

QT-FIT8 2x18

QT-FIT8 2x36

QT-FIT8 3x18, 4x18

QT-FIT8 3x36

QT-FIT8 2x58

QT-FIT8 2x58-70

QT-ECO 1x4-16/220-240 S

QT-ECO 1x4-16/220-240 L

QT-ECO 1x18-21/220-240 S

QT-ECO 2x5-11/220-240 S

QT-ECO 1x18-24/220-240 S

QT-ECO 1x18-24/220-240 L

QT-ECO 1x26/220-240 S

QT-COMBI 1x36/220-240

QT-COMBI 1x58/220-240

QT-ECO 1x18-24/220-240 LI

QT-ECO 1x4-16/220-240 LI

QT ENDURA 70-100/120-240 S

QT ENDURA 100-150/120-240 S

1051 04/2016