Abbott

Declaration of Conformity

Certificate Identification:	3L82
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-21, 3L82-41	53301	Glucose	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Digitally signed by Ceaicovschi Tudor
Date: 2023.01.17 17:58:39 EET
Reason: MoldSign Signature
Location: Moldova

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: November 17, 2014

Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 3P39

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P39-21; 3P39-41	53583	Uric Acid	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 6K01

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6K01-20	56676	Acid Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 7D53
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D53-23	53599	Albumin BCG	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 9D31
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D31-20	58236	Alkaline Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

Abbott

Declaration of Conformity

Certificate Identification: DoC-*7D55*-SD DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D55-22	52929	Alkaline Phosphatase	**Self-declared**
7D55-32	52929	Alkaline Phosphatase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: **Diana Romero**
Position: **Director Quality Assurance**
Date of Approval: 22-MAY-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 22-MAY-2017
Date Issued: 22-MAY-2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not applicable
Effective (Date or Lot Number): 22-MAY-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 7D58
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D58-21	52941	Amylase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification:	7D56
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-21	52925	Alanine Aminotransferase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 1E66

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E66-04	41830	Bilirubin Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: September 28, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

Declaration of Conformity

Certificate Identification: 8G63
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8G63-21	53236	Direct Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: September 3, 2015
Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D81
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6L45-21	53229	Total Bilirubin	Self-declared
6L45-41	53229	Total Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 12-Oct-2018

Signature: Mark Littlefield

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 12-OCT-2018

Date Issued: 12-OCT-2018

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 8,2017

Effective (Date or Lot Number): 12-OCT-2018

ABBOTT

Declaration of Conformity

Certificate Identification: 3L79

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L79-21;3L79-31; 3L79-41	45789	Calcium	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

Declaration of Conformity

Certificate Identification:	7D62
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D62-21	53362	Cholesterol	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 9-3-2015

Effective (Date or Lot Number): 8-SEP-2017

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

ABBOTT

Declaration of Conformity

Certificate Identification: 3L81

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L81-22; 3L81-32; 3L81-41	53251	Creatinine	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: July 16, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 1J72
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1J72-20	59058	Detergent A	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 2J94

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2J94-21	59058	Detergent B	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: December 4, 2014

Date Issued: December 4, 2014

Supersedes: New

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: December 4, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): December 4, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 7D65
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D65-21 7D65-41	53030	Gamma-Glutamyl Transferase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 9D29
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D29-20	56676	Water Bath Additive	Self-declared
9D29-21	56676	Water Bath Additive	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 6-11-2015
Date Issued: 6-11-2015
Supersedes: March 28,2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 6-11-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 6-11-2015

Abbott

Declaration of Conformity

Certificate Identification: 3L82
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-21, 3L82-41	53301	Glucose	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: 
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature: 
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: November 17, 2014
Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: DoC-4P5220, 4P5201, 4P5211-SD DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4P52-20	59090	Hemoglobin A1c Reagent	**Self-declared**
4P52-01	53315	Hemoglobin A1c Calibrator	**Self-declared**
4P52-11	44435	Hemoglobin A1c Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: **Diana Romero**
Position: **Director, Site QA**
Date of Approval: 17-NOV-2017

Signature: Mark Littlefield
Full Name: **Mark Littlefield**
Position: **Assoc. Director, Regulatory Affairs**
Date of Approval: 17-NOV-2017
Date Issued: 17-Nov-2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: N/A
Effective (Date or Lot Number): 17-Nov-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 3K33

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3K33-21	30169	Ultra HDL	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: April 4, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015

Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155324

Original approval(s):
ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate identity number: 10155324

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

MDSAP Facility Identifier: 079226220

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

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

Canada:
Medical Devices Regulations – Part 1- SOR 98/282

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

United States:
21 CFR 820
21 CFR 803
21 CFR 806

Cliff Muckleroy - Area Operations Manager Americas
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000846
Effective Date: 2018 October 13
Expiry Date: 2021 October 12
Certificate Issue Number: 10155325

Original Approval:
MDSAP/ ISO 13485 – 2017 December 7

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: http://www.lrqausa.com/help-and-support/Request-for-certificate-verification

Certificate Schedule

Certificate Issue Number: 10155325

Approval Number: MDSAP – 0015682

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring. Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: http://www.lrqausa.com/help-and-support/Request-for-certificate-verification

Issued By: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States

Certificate Schedule

Certificate Issue Number: 10155325

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	MDSAP 2017 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States MDSAP Facility Identifier: 079226220-002	MDSAP 2017 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States MDSAP Facility Identifier: 079226220-003	MDSAP 2017 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: http://www.lrqausa.com/help-and-support/Request-for-certificate-verification

Issued By: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SEKISUI DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	Sekisui Diagnostics (UK) Ltd Liphook Way Allington Maidstone Kent ME16 0LQ
Product:	Direct LDL Catalogue Number: 1E31-20; 1E31-02 GMDN Code: 53395; 41728
Classification:	General IVD
Conformity Assessment Route:	Annex III, self-certified

We hereby declare that the above mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Allington, UK

Signature: David Torrens 20-NOV-2018

David Torrens
Senior Manager Regulatory Affairs
Sekisui Diagnostics (UK) Ltd

Date

Sekisui Diagnostics (UK) Ltd
Liphook Way
Allington, Kent, ME16 0LQ
Tel: 01622 607800 Fax: 01622 607801
info@sekisui-dx.com
www.sekisuidiagnostics.com

ABBOTT

Declaration of Conformity

Certificate Identification: 3E16
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3E16-02	53109	Lipase Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification: 7D80
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D80-31	53114	Lipase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: November 17, 2014

Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 5P56

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
5P56-01	53356	Lipid Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: January 30, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

TECHNOPATH

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Catalogue Number
Multichem S Plus (Unassayed)	05P79-10
Multichem S Plus (Unassayed)	05P79-11
Multichem S Plus (Unassayed)	05P79-12
Multichem S Plus	CH100CRP
Multichem S Plus	CH101CRP
Multichem S Plus	CH102CRP
Multichem S Plus	CH103CRP
Multichem S Plus (Assayed)	05P78-10
Multichem S Plus (Assayed)	05P78-11
Multichem S Plus (Assayed)	05P78-12
Multichem S Plus (Unassayed)	CH110CRP.05
Multichem S Plus (Unassayed)	CH111CRP.05
Multichem S Plus (Unassayed)	CH112CRP.05
Multichem S Plus (Unassayed)	CH113CRP.05
Multichem S Plus	CH100PLA
Multichem S Plus	CH101PLA
Multichem S Plus	CH102PLA
Multichem S Plus	CH103PLA
Multichem S Plus (Assayed)	CH110PLA.05
Multichem S Plus (Assayed)	CH111PLA.05
Multichem S Plus (Assayed)	CH112PLA.05
Multichem S Plus (Assayed)	CH113PLA.05

TECHNOPATH

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2012/ ISO 13485:2003
QMS Certification No.:	LRQ 4008261/A
Issued By:	Lloyds Register LRQA, 71 Fenchurch Street, London EC3M 4BS United Kingdom.

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

Signed for and on behalf of Techno-path Manufacturing Ltd.,

Bernd Hass , Head of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

24-Jan-2014.
Date

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO 15223-1:2012	Symbols for use in the labelling of medical devices
ISO 13485:2012 + AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 13640:2002	Stability Testing of In vitro diagnostic reagents

ABBOTT

Declaration of Conformity

Certificate Identification: 1E65

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E65-04	30216	Multiconstituent Calibrator	Self-declared
1E65-05	30216	Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: March 6, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 7D73
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D73-21	53989	Total Protein	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories, 1921 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

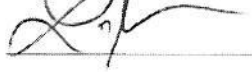
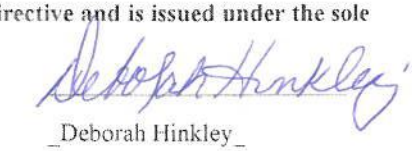
Certificate Identification:	ARCH Sys Acc LC	IRIS V3
Legal Manufacturer's Name:	Abbott Laboratories	
Legal Manufacturer's Address:	Diagnostics Division Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	NA	ARCHITECT Septum	**Self-declared**
4D19-01	NA	ARCHITECT Replacement Caps	**Self-declared**
7C14-01	NA	ARCHITECT Sample Cups	**Self-declared**
7C15-02	NA	ARCHITECT Reaction Vessels	**Self-declared**
7C15-03	NA	ARCHITECT Reaction Vessels	**Self-declared**

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	_Lauren Sieber_	Full Name:	_Deborah Hinkley_
Position:	Product Quality Assurance Manager	Position:	Regulatory Affairs Director
Date of Approval:	5|28|2015	Date of Approval:	5/29/2015
Date Issued:	06/02/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedes:	June 13, 2013	Effective (Date or Lot Number):	06/02/2015

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 & RSH Service

March 6th – 14th, 2018

Ali Güntekin		14.03.2018
TRAINER NAME	TRAINER SIGNATURE	DATE DD.MM.YYYY
ABBOTT DIAGNOSTICS		**Germany - Delkenheim**

Abbott

Abbott

Declaration of Conformity

Certificate Identification: 7D74
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D74-21	53462	Triglyceride	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: 9-3-2015
Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 7D75
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D75-21 7D75-31	53590	Urea Nitrogen	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Ireland

has established and applies
a Quality Management System for

Design, development and manufacture of
in vitro diagnostic test kits,
reagents and common liquid accessories.

An audit was performed, Order No. **707114974**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-04-01** until **2023-03-31**.

Certificate Registration No.: **12 100 59742 TMS**.

Product Compliance Management
Munich, 2020-03-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 001922 0022 Rev. 01

Holder of Certificate: **Abbott Ireland Diagnostics Division**
Finisklin Business Park
Sligo
IRELAND

Facility(ies): Abbott Ireland Diagnostics Division
Finisklin Business Park, Sligo, IRELAND

Certification Mark:

Scope of Certificate: **Design, develop and manufacture of in vitro diagnostic test kits, reagents and common liquid accessories for donor screening and/or the detection and/or monitoring of hepatitis, cancers, cardiac markers, congenital transmitted diseases, determination of congenital disorders of the foetus, endocrine disorders and haematological disorders, therapeutic drug monitoring and infectious viral diseases.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713178712-05

Valid from: 2020-04-24
Valid until: 2023-03-24

Date, 2020-04-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054869 0011 Rev. 00

Holder of Certificate: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

Facility(ies): Abbott Ireland Diagnostics Division
Lisnamuck, Longford, Co. Longford, IRELAND

Certification Mark:

Scope of Certificate: **Design, development, and production of reagents and software for in vitro diagnostic use.**
Design, development and manufacture of in vitro diagnostic test kits and reagents for clinical chemistry.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 054869 0011 Rev. 00

Report No.: 713189547

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-08-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

H. Shimosaka

Hiroshi Shimosaka
President
ERMA INC.

ITALCERT

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

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

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

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

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

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

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430,9020	20 L
	3430,9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459,9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832,9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823,1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431,1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511,1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416,0500	500 ml
CyMet™ H20	3853,1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425,0500	500 ml
CyMet™ Micro	3852,1000	1 L
CyMet™ Micro CN free	3863,1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

Declaration of CE conformity

Avantor Performance Materials B.V. reg. No. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
the Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T. Baker label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.
22 November 2011

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml
3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
Cleaners		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	1liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
Reagents for 5-part WBC diff. on STKS and MaxM.		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	Reticount™	30 ml
3777	Reticount CD	15 x 3.5 ml

Hematology Controls		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L,1 x N,1 x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L,N,H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers.		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline.		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
	Stains and Dyes	
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2,5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2,5 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
	Clearing agent	
3905.2500PE	UltraClear	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
	Mounting media	
3921.0500	UltraKitt	500 ml
3921.0600	UltraKitt	6 x 100 ml
	Fixatives	
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

22 November 2011

To whom this may concern

Date: March 01, 2021 Letter of Authorization

Avantor Performance Materials Poland S.A., reg. No. 0000010108 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histology located at:

Sowińskiego 11
44-101 Gliwice
Poland

herewith confirms that:

I.M Global Biomarketing Group Moldova S.R.L
Republic of Moldova
MD-2001, Chisinau
Tighina str. 65, 607 office
Tel (373 22) 549 120, 549 121
Fax (373 22) 547 373

is authorized to act as our distributor for our hematology/histology reagents and controls (Products) in Moldova
.
We declare that we will supply the Products for the needs of tenders.
We declare that we will supply the Products for tenders with warranty as per the Avantor General Conditions of Sale.

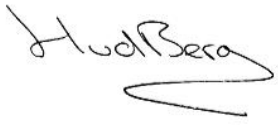
Furthermore I.M Global Biomarketing Group is duly entitled to:

- Register, promote, offer, negotiate prices and sell our Products in Moldova;
- carry out the required product training of the medical and technical personnel who will use these products.

The product specialists of I.M Global Biomarketing Group have been duly trained and are qualified for providing all services in regards to consulting, sales, maintenance and training.

In all the above activities I.M Global Biomarketing Group is acting in its own name and on its own account.
This authorization letter is valid until about 1 year after date.

Avantor Performance Materials S.A.
Poland



H van den Berg,
Marketing Product Manager Diagnostics

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA INC.

BeneSphera™

3 PART DIFFERENTIAL

Hematology Analyzer

BeneSphera™ **TRAINING**

Mr / ~~Ms~~ **Sergiu Sorocovici**

Global Biomarketing Group

str. Tighina 65, of. 607

2001 Chisinau, Moldau

has attended a 2-days training on goods manufactured or distributed by us.

April 12th – April 13th, 2012

Deventer, The Netherlands

Place, Date 13.04.2012

P.O. Box 1 - 0570-687500
AVANTOR PERFORMANCE MATERIALS B.V.
7400 AA DEVENTER - Holland

BeneSphera™ | AVANTOR™ PERFORMANCE MATERIALS

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

Certificate Number:	16880
EAC Code:	34
Certified Since:	March 22, 2012
Valid Until:	March 19, 2024
Reissued:	March 20, 2021
Cycle Issued:	March 20, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate of Registration

nqa global assurance

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Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

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For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	**: Clinical chemistry analyzer**
Product No.	**: 6003-400**
Model	**: Selectra ProM**
GMDN code	**: 56678**

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All other member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Certification by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	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	
	IEC 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	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	**Clinical chemistry analyzer, automated**
Model	**Selectra ProM**
Reference numbers	**6003-400**
GMDN code	**56678**
Accessories	**See separate document 'Regulatory status of parts & accessories'**

Product classification
As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure
In accordance with Annex III of the IVDD 98/79/EC

The product (including all accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL);
- All other member states of the European Union (EU);
- All member states of the European Free Trade Association (EFTA) and Switzerland.

Spankeren, August 2015

A. Altink

Managing Director

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	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	
	IEC 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	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

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

CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

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

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

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

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

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

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

ALLEGATO N. **9124.CRC4-1**
ANNEX N.

CERACARTA SPA

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

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

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

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Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

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CISQ is the Italian Federation of management system Certification Bodies.

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www.iqnet-certification.com

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

CSQ
www.imq.it

ALLEGATO N. **9124.CRC4-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
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CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

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

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

IAF: 07, 09, 19, 29, 12

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

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

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ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

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

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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CSQ
www.imq.it

ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

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

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com

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

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
VIA GRAMADORA 12/14 - 47122 FORLI' (FC)
has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2020 - 09 - 29**
Expires on: ***2023 - 10 - 07***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ 0117161

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.04ИБФ1.ОС23.0000308

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23

Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»

192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,

тел. +7 (812) 649-93-88, email: info@essert.ru

ВЫДАН

Закрытому акционерному обществу «ЭКОлаб»

ИНН 5035025076 ОГРН 1035007106958

Адрес: 142530, РФ, Московская область, г. Электрогорск, ул. Буденного, д. 1

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА МЕДИЦИНСКИХ ИЗДЕЛИЙ

применительно к работам согласно приложению № 1 к настоящему сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.0000308П от 30.06.2022

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ПромТех Стандарт

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130.

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ 0117162

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

РАЗРЕШЕНИЕ

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

Регистрационный номер РОСС RU.04ИБФ1.ОС23.0000308Р

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23

Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»

192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,

тел. :+7 (812) 649-93-88, email: info@essert.ru

ВЫДАНО

Закрытому акционерному обществу «ЭКОлаб»

ИНН 5035025076 ОГРН 1035007106958

Адрес: 142530, РФ, Московская область, г. Электрогорск, ул. Буденного, д. 1

на основании сертификата № РОСС RU.04ИБФ1.ОС23.0000308

Настоящее разрешение предоставляет право применения знака соответствия системы добровольной сертификации «ПРОМТЕХСТАНДАРТ»:

при маркировке продукции, при оказании работ (услуг), на бланках организации, в рекламно-информационных материалах, печатных изданиях, вывесках, выставочных стендах и т.д., на сайтах организации в сети Интернет, в соответствии с правилами применения знака соответствия системы добровольной сертификации "ПромТехСтандарт"

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ Система добровольной сертификации "ПромТех Стандарт" РОСС RU.32001.04ИБФ1.ОС23

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117163

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000720Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Овинникова Светлана Сергеевна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.000720ПЭ от 30.06.2022
и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" для сертификатов системы добровольной сертификации ПромТехСтандарт РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ А.В. Арендарь
подпись, инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись, инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117164

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000721Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23

Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Котляр Марина Анатольевна

соответствует требованиям

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок

системы менеджмента качества медицинских изделий

на соответствие требованиям стандарта

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,

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и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117165

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000722Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Трощенкова Елена Петровна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
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и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Руководитель органа _____ А.В. Арендарь
подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ 0117166

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000723Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23

Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»

192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,

тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нищакова Наталья Евгеньевна

соответствует требованиям

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок

системы менеджмента качества медицинских изделий

на соответствие требованиям стандарта

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,

протокол № РОСС RU.04ИБФ1.ОС23.000723ПЭ от 30.06.2022

и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ системы добровольной сертификации ПромТех Стандарт РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ А.В. Арендарь

подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов

подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117167

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000724Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Королева Татьяна Александровна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
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и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Руководитель органа _____ А.В. Арендарь
подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ № 0117168
«ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.04ИБФ1.ОС23.0000308
(является неотъемлемой частью сертификата соответствия)

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

Применительно к видам работ:

ОКВЭД:
46.46.2 - Торговля оптовая изделиями, применяемыми в медицинских целях

ОКВЭД 2:
21.20.2 Производство материалов, применяемых в медицинских целях
72.19 Научные исследования и разработки в области естественных и технических наук прочие
86.90.9 Деятельность в области медицины прочая, не включенная в другие группировки

Руководитель органа _____ А.В. Арендарь
подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 7

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS

Zone Industrielle

61500 SEES FRANCE

pour les activités

for the activities

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

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

réalisées sur le(s) site(s) de

performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

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

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

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

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Lionel DREUX
Certification Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 10462–7
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-6

ELITech Clinical Systems
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (7 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

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

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

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons les électrodes conformes à la Directive 2011/65/UE du parlement européen et du conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques incluant la DIRECTIVE DÉLÉGUÉE (UE) 2015/863 DE LA COMMISSION du 31 mars 2015 modifiant l'annexe II de la Directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la liste des substances soumises à limitations.

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (7 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

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

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

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify electrodes; conform to Directive 2011/65/EU 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, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (7 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

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

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

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos los electrodos conformes con la Directiva 2011/65/UE del parlamento europeo y del consejo del 8 de junio de 2011 sobre restricciones a la utilización de algunas sustancias peligrosas en aparatos eléctricos y electrónicos incluyendo la Directiva delegada (UE) 2015/863 de la comisión del 31 de marzo de 2015 por la que se modifica el anexo II de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo en cuanto a la lista de sustancias restringidas.

Sées, le 19 Mai 2022

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REF	PRODUCT NAME	GMDN Code
3918-004	Na electrode	52896
3918-005	K electrode	52892
3918-006	Cl electrode	52876
3918-003	CO2 electrode	60773
3918-002	Reference electrode	59241
ACUR-0055	URIC ACID Standard 6 mg/dL	44704
ALBU-0250	ALBUMIN	53597
ALBU-5220	ALBUMIN	53597
ALBU-0600	ALBUMIN	53597
ALBU-5600	ALBUMIN	53597
ALBU-0700	ALBUMIN	53597
ALBU-5700	ALBUMIN	53597
ALBU-M830	ALBUMIN	53597
ALBU-5M30	ALBUMIN	53597
ALPI-0230	ALP IFCC	52928
ALPI-5100	ALP IFCC	52928
ALPI-6050	ALP IFCC	52928
ALSL-0250	ALT/GPT 4+1 SL	52923
ALSL-5220	ALT/GPT 4+1 SL	52923
ALSL-6050	ALT/GPT 4+1 SL	52923
ALSL-0410	ALT/GPT 4+1 SL	52923
ALSL-5415	ALT/GPT 4+1 SL	52923
ALSL-6255	ALT/GPT 4+1 SL	52923
ALSL-0430	ALT/GPT 4+1 SL	52923
ALSL-0455	ALT/GPT 4+1 SL	52923
ALSL-0510	ALT/GPT 4+1 SL	52923
ALSL-5515	ALT/GPT 4+1 SL	52923
ALSL-6615	ALT/GPT 4+1 SL	52923
ALSL-M490	ALT/GPT	52923
ALSL-5M90	ALT/GPT	52923
ALSL-6M30	ALT/GPT	52923
AMSL-0230	AMYLASE SL	52940
AMSL-5220	AMYLASE SL	52940
AMSL-0390	AMYLASE SL	52940
AMSL-5405	AMYLASE SL	52940
AMSL-0400	AMYLASE SL	52940
AMSL-M430	AMYLASE	52940
AMSL-5M30	AMYLASE	52940
ASLO-0250	ANTI-STREPTOLYSIN O	59055
ASLO-5025	ANTI-STREPTOLYSIN O	59055
ASLO-6006	ANTI-STREPTOLYSIN O	59055
ASLO-4001	ANTI-STREPTOLYSIN O	51744
ASSL-0250	AST/GOT 4+1 SL	52954
ASSL-5220	AST/GOT 4+1 SL	52954
ASSL-6050	AST/GOT 4+1 SL	52954
ASSL-0410	AST/GOT 4+1 SL	52954
ASSL-5415	AST/GOT 4+1 SL	52954
ASSL-6255	AST/GOT 4+1 SL	52954
ASSL-0430	AST/GOT 4+1 SL	52954
ASSL-0455	AST/GOT 4+1 SL	52954
ASSL-0510	AST/GOT 4+1 SL	52954
ASSL-5515	AST/GOT 4+1 SL	52954
ASSL-6615	AST/GOT 4+1 SL	52954
ASSL-M490	AST/GOT	52954
ASSL-5M90	AST/GOT	52954
ASSL-6M30	AST/GOT	52954
AUML-0250	URIC ACID MONO SL	53583
AUML-5220	URIC ACID MONO SL	53583
AUML-0420	URIC ACID MONO SL	53583
AUML-5405	URIC ACID MONO SL	53583
AUML-0427	URIC ACID MONO SL	53583
AUML-0497	URIC ACID MONO SL	53583
AUML-5505	URIC ACID MONO SL	53583
AUML-0500	URIC ACID MONO SL	53583
AUML-0507	URIC ACID MONO SL	53583

REF	PRODUCT NAME	GMDN Code
AUML-0707	URIC ACID MONO SL	53583
AUML-5710	URIC ACID MONO SL	53583
AUML-M830	URIC ACID	53583
AUML-5M30	URIC ACID	53583
AUSL-0250	URIC ACID SL	53583
AUSL-5220	URIC ACID SL	53583
AUSL-6050	URIC ACID SL	53583
BIDI-0250	BILIRUBIN DIRECT 4+1	53233
BIDI-5220	BILIRUBIN DIRECT 4+1	53233
BIDI-6050	BILIRUBIN DIRECT 4+1	53233
BIDI-0600	BILIRUBIN DIRECT 4+1	53233
BIDI-0500	BILIRUBIN DIRECT	53233
BIDI-5600	BILIRUBIN DIRECT	53233
BITD-6250	BILIRUBIN DIRECT	53233
BIDI-M430	DIRECT BILIRUBIN	53233
BIDI-5M30	DIRECT BILIRUBIN	53233
BIDI-6M10	DIRECT BILIRUBIN	53233
BIDV-0850	DIRECT BILIRUBIN ENVOY	53233
BITD-0600	BILIRUBIN TOTAL & DIRECT 4+1	53229/53233
BITO-0250	BILIRUBIN TOTAL 4+1	53229
BITO-5220	BILIRUBIN TOTAL 4+1	53229
BITO-6050	BILIRUBIN TOTAL 4+1	53229
BITO-0600	BILIRUBIN TOTAL 4+1	53229
BITO-5600	BILIRUBIN TOTAL 4+1	53229
BITD-6400	BILIRUBIN TOTAL 4+1	53229
BITO-M430	TOTAL BILIRUBIN	53229
BITO-5M30	TOTAL BILIRUBIN	53229
BITO-6M10	TOTAL BILIRUBIN	53229
BITV-0850	TOTAL BILIRUBIN ENVOY	53229
CALA-0250	CALCIUM ARSENAZO	45789
CALA-5220	CALCIUM ARSENAZO	45789
CALA-0600	CALCIUM ARSENAZO	45789
CALA-5600	CALCIUM ARSENAZO	45789
CALA-M430	CALCIUM ARSENAZO	45789
CALA-5M30	CALCIUM ARSENAZO	45789
CALI-0550	ELICAL 2	47868
CALI-1550	ELICAL 2	47868
CHDL-0250	HDL CHOLESTEROL	53391
CHDL-5021	HDL CHOLESTEROL	53391
CHDL-6014	HDL CHOLESTEROL	53391
CHDL-0600	HDL CHOLESTEROL	53391
CHDL-5090	HDL CHOLESTEROL	53391
CHDL-6060	HDL CHOLESTEROL	53391
CHDL-M330	HDL CHOLESTEROL	53391
CHDL-5M30	HDL CHOLESTEROL	53391
CHDL-6M30	HDL CHOLESTEROL	53391
CHEB-0250	CHOLINESTERASE	52971
CHEB-5008	CHOLINESTERASE	52971
CHEB-6005	CHOLINESTERASE	52971
CHES-0053	CHOLINESTERASE	52971
CHLO-0250	CHLORIDE	60037
CHLO-0600	CHLORIDE	60037
CHOL-0055	CHOLESTEROL Standard 200 mg/dL	44698
CHSL-0250	CHOLESTEROL SL	53359
CHSL-5220	CHOLESTEROL SL	53359
CHSL-0455	CHOLESTEROL SL	53359
CHSL-0497	CHOLESTEROL SL	53359
CHSL-5505	CHOLESTEROL SL	53359
CHSL-0500	CHOLESTEROL SL	53359
CHSL-0507	CHOLESTEROL SL	53359
CHSL-0700	CHOLESTEROL SL	53359
CHSL-5710	CHOLESTEROL SL	53359
CHSL-0707	CHOLESTEROL SL	53359
CHSL-M690	CHOLESTEROL	53359
CHSL-5M90	CHOLESTEROL	53359

REF	PRODUCT NAME	GMDN Code
CKMB-0900	CK-MB CONTROL	44693
CKMB-1030	CK-MB CONTROL	44693
CKSL-0230	CK NAC SL	53003
CKSL-5220	CK NAC SL	53003
CKSL-6050	CK NAC SL	53003
CKSL-0410	CK NAC SL	53003
CKSL-5405	CK NAC SL	53003
CKSL-6255	CK NAC SL	53003
CKSL-0430	CK NAC SL	53003
CKSL-M230	CK NAC	53003
CKSL-5M30	CK NAC	53003
CKSL-6M10	CK NAC	53003
CLDL-0250	LDL CHOLESTEROL	53395
CLDL-5021	LDL CHOLESTEROL	53395
CLDL-6014	LDL CHOLESTEROL	53395
CLDL-M330	LDL CHOLESTEROL	53395
CLDL-5M30	LDL CHOLESTEROL	53395
CLDL-6M30	LDL CHOLESTEROL	53395
CMSL-0230	CK-MB	52994
CMSL-5220	CK-MB	52994
CMSL-6220	CK-MB	52994
CMSL-WR	CK-MB	52994
CMSL-0410	CK-MB SL	52994
CMSL-5405	CK-MB SL	52994
CMSL-6255	CK-MB SL	52994
CONT-0060	ELITROL I	47869
CONT-1060	ELITROL I	47869
CONT-0160	ELITROL II	47869
CONT-1160	ELITROL II	47869
CRCO-0600	CREATININE JAFFE	53251
CRCO-5600	CREATININE JAFFE	53251
CRCO-6600	CREATININE JAFFE	53251
CRCO-0700	CREATININE JAFFE	53251
CRPW-0043	CRP WR CALIBRATOR SET	41838
CRPW-0045	CRP WR CONTROL	41839
CRPW-0230	CRP WR	53705
CRPW-0850	CRP WR ENVOY	53705
CRSL-0250	CREATININE PAP SL	53250
CRSL-5221	CREATININE PAP SL	53250
CRSL-6070	CREATININE PAP SL	53250
CRSL-0630	CREATININE PAP SL	53250
CRSL-5505	CREATININE PAP SL	53250
CRSL-6470	CREATININE PAP SL	53250
CRSL-M490	CREATININE PAP	53250
CRSL-5M90	CREATININE PAP	53250
CRSL-6M30	CREATININE PAP	53250
FEFE-0230	IRON FERENE	54758
FEFE-5140	IRON FERENE	54758
FEFE-6040	IRON FERENE	54758
FEFE-0600	IRON FERENE	54758
FEFE-5600	IRON FERENE	54758
FEFE-6400	IRON FERENE	54758
FEFE-0850	IRON ENVOY	54758
FEFE-M230	IRON FERENE	54758
FEFE-5M30	IRON FERENE	54758
FEFE-6M10	IRON FERENE	54758
GHSL-0250	GLUCOSE HK SL	53301
GHSL-5220	GLUCOSE HK SL	53301
GHSL-6050	GLUCOSE HK SL	53301
GHSL-0600	GLUCOSE HK SL	53301
GHSL-5505	GLUCOSE HK SL	53301
GHSL-6605	GLUCOSE HK SL	53301
GHSL-M490	GLUCOSE HK	53301
GHSL-5M90	GLUCOSE HK	53301
GHSL-6M30	GLUCOSE HK	53301

REF	PRODUCT NAME	GMDN Code
GISL-0250	GAMMA-GT PLUS SL	53027
GISL-5220	GAMMA-GT PLUS SL	53027
GISL-6050	GAMMA-GT PLUS SL	53027
GISL-0400	GAMMA-GT PLUS SL	53027
GISL-0420	GAMMA-GT PLUS SL	53027
GISL-5405	GAMMA-GT PLUS SL	53027
GISL-6255	GAMMA-GT PLUS SL	53027
GISL-M230	GAMMA-GT	53027
GISL-5M30	GAMMA-GT	53027
GISL-6M10	GAMMA-GT	53027
GLUP-0055	GLUCOSE Standard 100 mg/dL	41818
GPSL-0250	GLUCOSE PAP SL	53301
GPSL-5220	GLUCOSE PAP SL	53301
GPSL-0455	GLUCOSE PAP SL	53301
GPSL-0497	GLUCOSE PAP SL	53301
GPSL-5505	GLUCOSE PAP SL	53301
GPSL-0500	GLUCOSE PAP SL	53301
GPSL-0507	GLUCOSE PAP SL	53301
GPSL-0700	GLUCOSE PAP SL	53301
GPSL-5710	GLUCOSE PAP SL	53301
GPSL-0707	GLUCOSE PAP SL	53301
GPSL-M690	GLUCOSE PAP	53301
GPSL-5M90	GLUCOSE PAP	53301
HBAC-0043	HbA1c CALIBRATOR SET	53315
HBAC-4301	HbA1c CALIBRATOR SET	53315
HBAC-4302	HbA1c CALIBRATOR SET	53315
HBAC-4303	HbA1c CALIBRATOR SET	53315
HBAC-4304	HbA1c CALIBRATOR SET	53315
HBAC-0049	HbA1c CONTROL L + H	44435
HBAC-4605	HbA1c CONTROL L + H	44435
HBAC-4705	HbA1c CONTROL L + H	44435
HBAC-0240	HbA1c	59090
HBAC-5224	HbA1c	59090
HBAC-6076	HbA1c	59090
HBAC-6004	HbA1c	59090
HBAC-7225	HbA1c	59090
HBAE-0043	HbA1c Enzymatic Calibrator Set	53315
HBAE-4301	HbA1c Enzymatic Calibrator Set	53315
HBAE-4303	HbA1c Enzymatic Calibrator Set	53315
HBAE-M130	HbA1c Enzymatic	63151
HBAE-5M30	HbA1c Enzymatic	63151
HBAE-6M30	HbA1c Enzymatic	63151
HBAE-7050	HbA1c Enzymatic	63151
HDLL-0011	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0041	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0230	CHOLESTEROL HDL SL 2G	53391
HDLL-0380	CHOLESTEROL HDL SL 2G	53391
HDLL-0390	CHOLESTEROL HDL SL 2G	53391
HLCA-0041	HDL LDL CALIBRATOR	47868
HLCA-4001	HDL LDL CALIBRATOR	47868
ICRP-0043	CRP IP CALIBRATOR SET	41838
ICRP-4311	CRP IP CALIBRATOR SET	41838
ICRP-4312	CRP IP CALIBRATOR SET	41838
ICRP-4313	CRP IP CALIBRATOR SET	41838
ICRP-4314	CRP IP CALIBRATOR SET	41838
ICRP-4315	CRP IP CALIBRATOR SET	41838
ICRP-0046	CRP IP CONTROL I	41839
ICRP-4610	CRP IP CONTROL I	41839
ICRP-0047	CRP IP CONTROL II	41839
ICRP-4710	CRP IP CONTROL II	41839
ICRP-0400	CRP IP	53705
ICRP-6125	CRP IP	53705
ICRP-5025	CRP IP	53705
ICRP-M230	CRP IP	53705
ICRP-6M30	CRP IP	53705

REF	PRODUCT NAME	GMDN Code
ICRP-5M30	CRP IP	53705
IFRT-0042	FERRITIN CALIBRATOR	41927
IFRT-4230	FERRITIN CALIBRATOR	41927
IFRT-0230	FERRITIN	53718
IFRT-5020	FERRITIN	53718
IFRT-6005	FERRITIN	53718
IHAP-0400	HAPTOGLOBIN IP	53737
IHAP-6125	HAPTOGLOBIN IP	53737
IHAP-5025	HAPTOGLOBIN IP	53737
IIGA-0400	IgA IP	53760
IIGA-6125	IgA IP	53760
IIGA-5025	IgA IP	53760
IIGG-0400	IgG IP	53787
IIGG-6125	IgG IP	53787
IIGG-5025	IgG IP	53787
IIGM-0400	IgM IP	53795
IIGM-6125	IgM IP	53795
IIGM-5025	IgM IP	53795
IMAL-0043	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4311	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4312	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4313	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4314	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4315	µALBUMIN IP CALIBRATOR SET	53477
IMAL-0046	µALBUMIN IP CONTROL I	53478
IMAL-4610	µALBUMIN IP CONTROL I	53478
IMAL-0047	µALBUMIN IP CONTROL II	53478
IMAL-4710	µALBUMIN IP CONTROL II	53478
IMAL-0400	µALBUMIN IP	53475
IMAL-6125	µALBUMIN IP	53475
IMAL-5025	µALBUMIN IP	53475
IMAL-M230	MICROALBUMIN IP	53475
IMAL-6M30	MICROALBUMIN IP	53475
IMAL-5M30	MICROALBUMIN IP	53475
IORO-0400	OROSOMUCOID IP	53606
IORO-6125	OROSOMUCOID IP	53606
IORO-5025	OROSOMUCOID IP	53606
IPAL-0400	PREALBUMIN IP	53957
IPAL-6125	PREALBUMIN IP	53957
IPAL-5025	PREALBUMIN IP	53957
IPRO-0043	PROTEIN IP CALIBRATOR SET	53593
IPRO-4311	PROTEIN IP CALIBRATOR SET	53593
IPRO-4312	PROTEIN IP CALIBRATOR SET	53593
IPRO-4313	PROTEIN IP CALIBRATOR SET	53593
IPRO-4314	PROTEIN IP CALIBRATOR SET	53593
IPRO-4315	PROTEIN IP CALIBRATOR SET	53593
IRCT-0046	RHEUMATOLOGY CONTROL I	47869
IRCT-4610	RHEUMATOLOGY CONTROL I	47869
IRCT-0047	RHEUMATOLOGY CONTROL II	47869
IRCT-4710	RHEUMATOLOGY CONTROL II	47869
IRFA-0042	RF CALIBRATOR	42230
IRFA-4220	RF CALIBRATOR	42230
IRFA-0230	RHEUMATOID FACTOR	55111
IRFA-5020	RHEUMATOID FACTOR	55111
IRFA-6005	RHEUMATOID FACTOR	55111
ISCA-0250	ISE CALIBRATORS	52867
ISCA-4221	ISE CALIBRATORS	52867
ISCA-4222	ISE CALIBRATORS	52867
ISCT-0046	ISE CONTROL I	47869
ISCT-0047	ISE CONTROL II	47869
ISDI-0250	ISE DILUENT	58237
ISDI-5220	ISE DILUENT	58237
ISRS-0800	ISE REFERENCE SOLUTION	59238
ITRF-0400	TRANSFERRIN IP	59041
LACI-0250	LACTATE	53342

REF	PRODUCT NAME	GMDN Code
LACI-5008	LACTATE	53342
LACI-6005	LACTATE	53342
LACT-0100	LACTATE	53342
LDLL-0011	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0041	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0230	CHOLESTEROL LDL SL 2G	53395
LDLL-0380	CHOLESTEROL LDL SL 2G	53395
LDLL-0390	CHOLESTEROL LDL SL 2G	53395
LLSL-0230	LDH-L SL	53072
LLSL-5220	LDH-L SL	53072
LLSL-6050	LDH-L SL	53072
LLSL-0400	LDH-L SL	53072
LLSL-5400	LDH-L SL	53072
LLSL-6250	LDH-L SL	53072
LLSL-0420	LDH-L SL	53072
LLSL-M230	LDH IFCC	53072
LLSL-5M30	LDH IFCC	53072
LLSL-6M10	LDH IFCC	53072
LPSL-0230	LIPASE SL	53108
LPSL-0250	LIPASE	53108
LPSL-5088	LIPASE	53108
LPSL-6061	LIPASE	53108
LPSL-0850	LIPASE ENVOY	53108
LXCR-0112	CRP LATEX	53707
MAGX-0230	MAGNESIUM XYLIDYL	46795
MAGX-0600	MAGNESIUM XYLIDYL	46795
MAGX-0850	MAGNESIUM ENVOY	46795
MGXB-0250	MAGNESIUM XB	46795
MGXB-5220	MAGNESIUM XB	46795
MGXB-0600	MAGNESIUM XB	46795
MGXB-5600	MAGNESIUM XB	46795
MGXB-M430	MAGNESIUM XB	46795
MGBX-5M30	MAGNESIUM XB	46795
PASL-0230	ALP (DEA) SL	52928
PASL-5220	ALP (DEA) SL	52928
PASL-6050	ALP (DEA) SL	52928
PASL-0400	ALP (DEA) SL	52928
PASL-5405	ALP (DEA) SL	52928
PASL-6255	ALP (DEA) SL	52928
PASL-0420	ALP (DEA) SL	52928
PHOS-0230	PHOSPHORUS	59123
PHOS-5220	PHOSPHORUS	59123
PHOS-0600	PHOSPHORUS	59123
PHOS-5600	PHOSPHORUS	59123
PHOS-M430	PHOSPHORUS	59123
PHOS-5M30	PHOSPHORUS	59123
PIVD-0850	ALP ENVOY	52928
PROB-0250	TOTAL PROTEIN PLUS	53985
PROB-5220	TOTAL PROTEIN PLUS	53985
PROB-0600	TOTAL PROTEIN PLUS	53985
PROB-5600	TOTAL PROTEIN PLUS	53985
PROB-0700	TOTAL PROTEIN PLUS	53985
PROB-5700	TOTAL PROTEIN PLUS	53985
PROB-M830	TOTAL PROTEIN	53985
PROB-5M30	TOTAL PROTEIN	53985
PRTU-0022	MICROPROTEIN PLUS Standard 100 mg/dL	53482
PRTU-0250	MICROPROTEIN PLUS	53481
PRTU-0600	MICROPROTEIN PLUS	53481
PRTU-5600	MICROPROTEIN PLUS	53481
PRTU-M230	URINE PROTEIN	53481
PRTU-5M30	URINE PROTEIN	53481
RHFA-M130	RHEUMATOID FACTOR	55111
RHFA-5M30	RHEUMATOID FACTOR	55111
RHFA-6M30	RHEUMATOID FACTOR	55111
RHFA-4220	RHEUMATOID FACTOR	42230

REF	PRODUCT NAME	GMDN Code
TGML-0250	TRIGLYCERIDES SL	53460
TGML-5220	TRIGLYCERIDES SL	53460
TGML-0425	TRIGLYCERIDES MONO SL NEW	53460
TGML-5415	TRIGLYCERIDES MONO SL NEW	53460
TGML-0427	TRIGLYCERIDES MONO SL NEW	53460
TGML-0455	TRIGLYCERIDES SL	53460
TGML-0497	TRIGLYCERIDES MONO SL NEW	53460
TGML-5515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0517	TRIGLYCERIDES MONO SL NEW	53460
TGML-0700	TRIGLYCERIDES MONO SL NEW	53460
TGML-5710	TRIGLYCERIDES MONO SL NEW	53460
TGML-0707	TRIGLYCERIDES MONO SL NEW	53460
TGML-M690	TRIGLYCERIDES	53460
TGML-5M90	TRIGLYCERIDES	53460
TIBC-0250	Direct TIBC	53904
TIBC-5025	Direct TIBC	53904
TIBC-6007	Direct TIBC	53904
TIBC-M130	Direct TIBC	53904
TIBC-5M30	Direct TIBC	53904
TIBC-6M30	Direct TIBC	53904
TRF2-M230	TRANSFERRIN	59041
TRF2-5M30	TRANSFERRIN	59041
TRF2-6M10	TRANSFERRIN	59041
TRIG-0055	TRIGLYCERIDES Standard 200 mg/dL	44702
URSL-0250	UREA UV SL	53587
URSL-5220	UREA UV SL	53587
URSL-6050	UREA UV SL	53587
URSL-0420	UREA UV SL	53587
URSL-5405	UREA UV SL	53587
URSL-6255	UREA UV SL	53587
URSL-0427	UREA UV SL	53587
URSL-0455	UREA UV SL	53587
URSL-0500	UREA UV SL	53587
URSL-5505	UREA UV SL	53587
URSL-6605	UREA UV SL	53587
URSL-0507	UREA UV SL	53587
URSL-M830	UREA	53587
URSL-5M30	UREA	53587
URSL-6M10	UREA	53587
URUV-0055	UREA Standard 50 mg/dL	53588
VITD-0043	VITAMIN D CALIBRATOR SET	54474
VITD-4311	VITAMIN D CALIBRATOR SET	54474
VITD-4312	VITAMIN D CALIBRATOR SET	54474
VITD-4313	VITAMIN D CALIBRATOR SET	54474
VITD-4314	VITAMIN D CALIBRATOR SET	54474
VITD-4315	VITAMIN D CALIBRATOR SET	54474
VITD-0049	VITAMIN D CONTROL SET	54475
VITD-4630	VITAMIN D CONTROL SET	54475
VITD-4730	VITAMIN D CONTROL SET	54475
VITD-0250	VITAMIN D	54476
VITD-5021	VITAMIN D	54476
VITD-6005	VITAMIN D	54476

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.
370 West 1700 South
Logan
Utah
84321
USA

Holds Certificate No: **FM 703046**

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

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-12
Latest Revision Date: 2021-12-23

Effective Date: 2022-01-11
Expiry Date: 2025-01-10

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