ABAXIS Europe GmbH • Bunsenstr. 9-11 • 64347 Griesheim • Germany

Griesheim, January 2024

RE: Piccolo Xpress® Chemistry Analyzer System

PRODUCT COMPATIBILITY

UNDER REGULATION (EU) 2017/746 and DIRECTIVE 98/79/EC

To whom it may concern

Please be informed that the Abaxis Piccolo Xpress® chemistry analyzer and associated reagent discs are in compliance with the applicable European In Vitro Diagnostic rules.

The In Vitro Device Regulation (EU) 2017/746 (IVDR), classified as devices for near-patient testing, is gradually replacing the In Vitro Diagnostic Directive 98/79/EC (IVDD).

Compliance with the IVDR does not result in a change to the product or intended use. New consumables can be used on analyzers previously certified under the IVDD.

Additionally, instructions for use, box and pouch labels are gradually being transitioned to comply with the new regulation.

Yours sincerely,
Abaxis Europe GmbH

DECLARATION OF CONFORMITY

MANUFACTURER:
Abaxis, Inc.
3240 Whipple Road
Union City, CA 94587, USA
SRN: US-MF-000021651

AUTHORIZED EUROPEAN UNION REPRESENTATIVE:
ABAXIS Europe, GmbH
Bunsenstr. 9-11
64347 Griesheim, Germany
SRN: DE-AR-000017984

THE DIRECTIVES COVERED BY THIS DECLARATION:
In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746;
Reduction of Hazardous Substances Directive (EU) 2011/65/EU including amendments 2015/863/EU and 2017/2102/EU

THE PRODUCTS COVERED BY THIS DECLARATION:

Trade Name	Basic UDI-DI	REF	#
Piccolo Xpress chemistry analyzer	++EABA11000000E7F	1100-0000E	1100-1001
Piccolo Xpress chemistry analyzer, Recertified	++EABA11000000ER5X	1100-0000ER	1100-1001R

CLASSIFICATION: 2017/746EU Class A – rule 5(b), 2011/65/EU Category 8 – Medical Device

THE BASIS ON WHICH CONFORMITY IS BEING DECLARED

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The Piccolo Xpress chemistry analyzer is classified as Class A and assessed utilizing the IVDR 2017/746/EU pathway Annex IX "Quality Management System and on Assessment of Technical Documentation"" and Annex IV "EU Declaration of Conformity".

The manufacturer hereby declares under his sole responsibility that the above mentioned products meet the provisions of Regulation 2017/746EU for in-vitro diagnostic medical devices and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment including amendments by directive 2015/863/EU for Annex II of 2011/65/EU.

See Attachment A for all Standards Applied. All supporting documentation is retained at the premises of the manufacturer.

SIGNATURE: _____ **DATE:** 07/15/2022

Toni Butikofer
Site Quality Lead

ABAXIS

DECLARATION OF CONFORMITY

Attachment A: Standards Applied

Standard	Title
EN ISO 13485:2016	Medical devices-Quality Management Systems- Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices-application of risk management to medical devices
EN ISO 15223-1:2021	Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling and Information to Be Supplied
IEC 61010-1:2010/AMD1:2016 EN 61010-1:2010/A1:2019	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1; General Requirements
IEC 61010-2-010:2019 EN 61010-2-010:2020	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 61010-2-020:2016 EN 61010-2-020:2017	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-020: Particular Requirements for Laboratory Centrifuges
IEC 61010-2-101:2018 EN 61010-2-101:2017	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
EN 61326-1:2013	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
EN 61326-2-6:2013 EN 61326-2-6:2021	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements - Part 2-6: Particular Requirements – In Vitro Diagnostic (IVD) Medical Equipment
EN 62304:2006	Medical Device Software: Software Life Cycle Processes
EN 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 62366:2015	Application of Usability Engineering to Medical Devices
EN ISO 17511:2003	Metrological Traceability of Values Assigned to Calibrators and Control Materials
EN ISO 20417:2021	Medical Devices — Information To Be Supplied By The Manufacturer
EN ISO/TR 20416:2020	Medical Devices — Post-market Surveillance For Manufacturers
ANSI/HIBC SLS:2.6	Supplier Labeling Standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757082 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757082 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Liver Panel Plus, used with the Piccolo Xpress® (EI) chemistry analyzer, utilizes dry and liquid reagents to provide *in vitro* quantitative determinations of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin, and total protein in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location/ near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Liver Panel Plus	400-0003	IVR 0602	Class C near-patient test	++EABA4000003GT
Piccolo® EI Liver Panel Plus	400-7060EI	IVR 0602	Class C near-patient test	++EABA4000003EIBL

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757082 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512760	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757083 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757083 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) General Chemistry 6 used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, gamma glutamyltransferase (GGT), glucose, and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® General Chemistry 6	400-0006	IVR 0602	Class C near-patient test	++EABA4000006GZ
Piccolo® EI General Chemistry 6	400-7083EI	IVR 0602	Class C near-patient test	++EABA4000006EIC3

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757083 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512761	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757084 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757084 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Electrolyte Panel reagent disc, used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the in vitro quantitative determination of chloride, potassium, sodium and total carbon dioxide in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Electrolyte Panel	400-0022	IVR 0608	Class C near-patient test	++EABA4000022GX
Piccolo® EI Electrolyte Panel	400-7116EI	IVR 0608	Class C near-patient test	++EABA4000022EIBV

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757084 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512762	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757085 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757085 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® MetLyte 8 Panel, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® MetLyte 8 Panel	400-0023	IVR 0602	Class C near-patient test	++EABA4000023GZ

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757085 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512763	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757087 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757087 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Basic Metabolic Panel, used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of calcium, chloride, creatinine, glucose, potassium, sodium, total carbon dioxide, and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Basic Metabolic Panel	400-0024	IVR 0602	Class C near-patient test	++EABA4000024H3
Piccolo® EI Basic Metabolic Panel	400-7128EI	IVR 0602	Class C near-patient test	++EABA4000024EIC7

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757087 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512764	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757088 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757088 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Lipid Panel reagent disc, used with the Piccolo Xpress® (EI) Chemistry analyzer, is intended for the *in vitro* quantitative determination of total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL), and triglycerides (TRIG) in capillary (fingerstick) lithium heparinized whole blood, venous lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing. From these determinations low-density lipoprotein cholesterol (LDL), very low-density lipoprotein cholesterol (VLDL), non-HDL cholesterol, and a total cholesterol / high-density lipoprotein cholesterol ratio (TC/H) are calculated by the analyzer. Lipid measurements are used in the diagnosis and treatment of lipid and lipoprotein disorders, atherosclerosis, various liver and renal diseases, diabetes mellitus, and other diseases involving lipid metabolism or various endocrine disorders.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Lipid Panel	400-0025	IVR 0608	Class B near-patient test	++EABA4000025H5
Piccolo® EI Lipid Panel	400-7144EI	IVR 0608	Class B near-patient test	++EABA4000025EICC

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757088 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512765	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757089 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757089 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® Hepatic Function Panel, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determinations of alanine aminotransferase, albumin, alkaline phosphatase, aspartate aminotransferase, direct bilirubin, total bilirubin, and total protein in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of- care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Hepatic Function Panel	400-0026	IVR 0608	Class B near-patient test	++EABA4000026H7

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757089 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512766	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757090 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

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Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757090 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® Renal Function Panel, used with the Piccolo Xpress® chemistry analyzer is intended to be used for the *in vitro* quantitative determination of albumin, calcium, chloride, creatinine, glucose, phosphorus, potassium, sodium, total carbon dioxide and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Renal Function Panel	400-0027	IVR 0602	Class C near-patient test	++EABA4000027H9

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757090 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512767	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757091 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757091 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Comprehensive Metabolic Panel, used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin, total carbon dioxide, total protein, and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Comprehensive Metabolic Panel	400-0028	IVR 0602	Class C near-patient test	++EABA4000028HB
Piccolo® EI Comprehensive Metabolic Panel	400-7139EI	IVR 0602	Class C near-patient test	++EABA4000028EICT

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757091 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512768	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757092 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757092 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) General Chemistry 13 used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), calcium, creatinine, gamma glutamyltransferase (GGT), glucose, total bilirubin, total protein, blood urea nitrogen (BUN), and uric acid in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® General Chemistry 13	400-0029	IVR 0602	Class C near-patient test	++EABA4000029HD
Piccolo® EI General Chemistry 13	400-7149EI	IVR 0602	Class C near-patient test	++EABA4000029EICY

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757092 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512769	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757093 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757093 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Lipid Panel Plus, used with the Piccolo Xpress® (EI) chemistry analyzer, is intended for the *in vitro* quantitative determination of total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL), triglycerides (TRIG), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and glucose (GLU) in capillary (fingerstick) lithium heparinized whole blood, venous lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing. From the CHOL, HDL and TRIG determinations, low-density lipoprotein cholesterol (LDL), very low-density lipoprotein cholesterol (VLDL), non-HDL cholesterol, and a total cholesterol / high-density lipoprotein cholesterol ratio (TC/H) are calculated by the analyzer. Lipid measurements are used in the diagnosis and treatment of lipid and lipoprotein disorders, atherosclerosis, various liver and renal diseases, diabetes mellitus, and other diseases involving lipid metabolism or various endocrine disorders.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Lipid Panel Plus	400-0030	IVR 0602	Class C near-patient test	++EABA4000030GW
Piccolo® EI Lipid Panel Plus	400-7155EI	IVR 0602	Class C near-patient test	++EABA4000030EIBS

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757093 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512770	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757096 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757096 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® Basic Metabolic Panel Plus, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of calcium, chloride, creatinine, glucose, lactate dehydrogenase, magnesium, potassium, sodium, total carbon dioxide, and blood urea nitrogen in a clinical laboratory setting or point-of-care location / near-patient testing. This disc is for testing heparinized plasma and serum, only.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Basic Metabolic Panel Plus	400-0031	IVR 0602	Class C near-patient test	++EABA4000031GY

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757096 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512771	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757097 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757097 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® (EI) Kidney Check, used with the Piccolo Xpress® (EI) chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of creatinine and blood urea nitrogen (BUN) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® Kidney Check	400-0033	IVR 0608	Class B near-patient test	++EABA4000033H4
Piccolo® EI Kidney Check	400-7165EI	IVR 0608	Class B near-patient test	++EABA4000033EIC9

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757097 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512772	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757099 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757099 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® MetLyte Plus CRP reagent disc, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of c-reactive protein (CRP), chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and blood urea nitrogen (BUN) in lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing. The Abaxis CRP method is not intended for high sensitivity CRP measurement.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® MetLyte Plus CRP	400-0034	IVR 0602, IVR 0506	Class C near-patient test	++EABA4000034H6

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757099 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512773	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757101 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757101 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® BioChemistry Panel Plus, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), amylase, aspartate aminotransferase (AST), c-reactive protein (CRP), calcium, creatinine, gamma glutamyltransferase (GGT), glucose, total protein, blood urea nitrogen (BUN), and uric acid in lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing. The Abaxis CRP method is not intended for high sensitivity CRP measurement.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® BioChemistry Panel Plus	400-0035	IVR 0602, IVR 0506	Class C near-patient test	++EABA4000035H8

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757101 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512774	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757102 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757102 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® MetLac 12 Panel reagent disc, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of albumin, calcium, chloride, creatinine, glucose, lactate, magnesium, phosphorus, potassium, sodium, total carbon dioxide and blood urea nitrogen (BUN) in lithium heparinized whole blood or lithium heparinized plasma in a clinical laboratory setting or point-of-care location / near-patient testing.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® MetLac 12 Panel	400-0037	IVR 0602	Class C near-patient test	++EABA4000037HC

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757102 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512775	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757103 R000

Manufacturer: Abaxis, Inc.

Address:
3240 Whipple Road
Union City
California
94587
USA

Single Registration Number: US-MF-000021651

EU Authorised Representative: Abaxis Europe GmbH

Address:
Bunsenstrasse 9-11
Greisheim
64347
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757103 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Piccolo® AmLyte 13, used with the Piccolo Xpress® chemistry analyzer, is intended to be used for the *in vitro* quantitative determination of alanine aminotransferase (ALT), albumin, amylase, aspartate aminotransferase (AST), calcium, c-reactive protein (CRP), creatine kinase, creatinine, glucose, potassium, sodium, total bilirubin and blood urea nitrogen (BUN) in lithium heparinized whole blood, lithium heparinized plasma, or serum in a clinical laboratory setting or point-of-care location / near-patient testing. The Abaxis CRP method is not intended for high sensitivity CRP measurement.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Piccolo® AmLyte 13	400-0041	IVR 0602, IVR 0506	Class C near-patient test	++EABA4000041H3

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 757103 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3512776	Issued

First Issue Date: **2023-06-06**

Current Issue Date: **2023-06-06**

Starting Validity Date: **2023-06-06**

Expiry Date: **2028-06-05**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

Elenco dispositivi individuati

Dati aggiornati al:06/01/2024

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1197000	S	1100-0000E	PICCOLO XPRESS® CHEMISTRY ANALYZER	W02010199 - STRUMENTAZIONE PER CHIMICA CLINICA NON ALTRIMENTI CLASSIFICATA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351507	S	1100-0000EI	PICCOLO XPRESS® CHEMISTRY ANALYZER	W02010199 - STRUMENTAZIONE PER CHIMICA CLINICA NON ALTRIMENTI CLASSIFICATA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197321	S	400-0003	PICCOLO® LIVER PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351514	S	400-0003EI	PICCOLO® LIVER PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197857	S	400-0006	PICCOLO® GENERAL CHEMISTRY 6	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351517	S	400-0006EI	PICCOLO® GENERAL CHEMISTRY 6	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197860	S	400-0022	PICCOLO® ELECTROLYTE PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351520	S	400-0022EI	PICCOLO® ELECTROLYTE PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197861	S	400-0023	PICCOLO® METLYTE 8 PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351525	S	400-0023EI	PICCOLO® METLYTE 8 PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197863	S	400-0024	PICCOLO® BASIC METABOLIC PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351527	S	400-0024EI	PICCOLO® BASIC METABOLIC PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197865	S	400-0025	PICCOLO® LIPID PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351530	S	400-0025EI	PICCOLO® LIPID PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197867	S	400-0026	PICCOLO® HEPATIC FUNCTION PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197869	S	400-0027	PICCOLO® RENAL FUNCTION PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351533	S	400-0027EI	PICCOLO® RENAL FUNCTION PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197871	S	400-0028	PICCOLO® COMPREHENSIVE METABOLIC PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351539	S	400-0028EI	PICCOLO® COMPREHENSIVE METABOLIC PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. II)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197872	S	400-0029	PICCOLO® GENERAL CHEMISTRY 13	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE

Elenco dispositivi individuati

Dati aggiornati al:06/01/2024

DISPOSITIVO MEDICO/ASSEMBLATO										FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1351541	S	400-0029EI	PICCOLO® GENERAL CHEMISTRY 13	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. III)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197873	S	400-0030	PICCOLO® LIPID PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351543	S	400-0030EI	PICCOLO® LIPID PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. III)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197875	S	400-0031	PICCOLO® BASIC METABOLIC PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197877	S	400-0033	PICCOLO® KIDNEY CHECK	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1351544	S	400-0033EI	PICCOLO® KIDNEY CHECK	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	ST - Test autodiagnostici (non inclusi nell'all. III)	30/10/2015		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197879	S	400-0034	PICCOLO® METLYTE PLUS CRP	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197880	S	400-0035	PICCOLO® BIOCHEMISTRY PANEL PLUS	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197881	S	400-0037	PICCOLO® METLAC 12 PANEL	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE
Dispositivo	1197883	S	400-0041	PICCOLO® AMLYTE 13	W01010404 - PARAMETRI MULTIPLI (MISTI) - REAGENTI DI CHIMICA CLINICA	D.L.vo 332/2000	IVD - Altro tipo di IVD	08/08/2014		FABBRICANTE	ABAXIS, INCORPORATED			US
										MANDATARIO	ABAXIS EUROPE GMBH		259949586	DE