



HARMONIZED SYSTEMS

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO TRANSFORM YOUR LABORATORY



Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

ALINITY.COM

Alinity ci-series

YOUR VISION. **OUR INNOVATION.** DESIGNED FOR YOU, **BY YOU.**

Alinity is Abbott's next generation of systems that span key laboratory disciplines and are designed to simplify diagnostics and help you deliver results that drive better patient outcomes.

With Alinity, critical interactions between individuals, systems and informatics are streamlined, enabling you to redefine performance in your laboratory and your institution.

Alinity



Achieve **measurably better** healthcare performance with our **personalized solutions** consisting of our **resourceful advocates**, **harmonized systems** and **intelligent insights**.



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

ALINITY.

YOUR TOTAL LABORATORY SOLUTION, DESIGNED TO DELIVER:



UNIFORMITY

Standardize operations in your lab and across your network through common intuitive processes across systems.

- Intuitive, user-driven design simplifies touch points and interactions.
- Easy-to-use graphic user interface with common software and iconography provides a consistent experience.



FLEXIBILITY

Discover flexible solutions that help you adapt to the day-to-day and long-term unpredictability of changing lab volumes.

- Scalable design allows for module additions and system reconfiguration as needs change with growing testing volumes.
- Multiple track-connectivity options provide open, customized automation for third-party systems to connect multiple departments across the lab and network.**



OPERATIONAL PRODUCTIVITY

Utilize your laboratory's space to its fullest potential with compact systems that provide more tests per square meter.

- Increased sample and reagent load-up capacity means more tests per square meter for maximized throughput, resulting in a compact footprint.***
- Continuous reagent access maintains uptime without interruption to tests in progress for greater operational productivity.



CONFIDENCE

Have confidence in the results you deliver to physicians through proven technology and assay design.

- Error-proof design and proven technology provides accurate results across platforms.
- Assay harmonization to Clinical and Laboratory Standards Institute guidelines ensures clear performance parameter definitions.

**Alinity m track connectivity is not yet available.

***As compared to ARCHITECT i2000 and ARCHITECT c8000.

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO **TRANSFORM YOUR LABORATORY**

The Alinity ci-series consists of compact, **scalable systems** to **maximize throughput** and **efficiency**, making today's high-performing laboratories run at their best, today and into the future.



Alinity c
Clinical Chemistry



Alinity i
Immunoassay



Alinity ci-series
Integrated Clinical Chemistry
and Immunoassay



IMPROVE OPERATIONS ACROSS PLATFORMS WITH **COMMON USER EXPERIENCE**

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.

USER-DRIVEN DESIGN

Loading samples, prioritizing STATs, replacing reagent cartridges and bulk solutions and utilizing the user interface are just a few of the critical interactions that are consistent across systems.



Alinity ci-series

Integrated Clinical Chemistry and Immunoassay



Alinity h-series

Hematology



Alinity s

Blood and Plasma Screening



Alinity m

Molecular



FLEXIBILITY

SEAMLESS SCALABILITY THAT ADAPTS TO CHANGING LABORATORY VOLUMES

Alinity ci-series



INTEGRATE UP TO FOUR MODULES IN VARYING COMBINATIONS

- The **flexible and scalable** Alinity ci-series offers increased throughput and capacity, allowing you to easily add modules as your volume grows, without replacing your current systems.
- **Integrate up to four modules** of multiple clinical chemistry and immunoassay systems, up to 14 configurations, all controlled by a single system control module.



OPERATIONAL PRODUCTIVITY

INNOVATIVE ENGINEERING FOR **MAXIMUM THROUGHPUT AND CAPACITY**

In today's uncertain environment, labs need to be able to quickly adapt to daily changes, as well as plan for the long term to ensure consistent delivery of services.



PERFORM MORE TESTS PER SQUARE METER***

Even when faced with limited space and resources, Alinity can more efficiently and effectively process **increased volumes** in a compact footprint.

Innovative engineering, combined with the **space-saving design** of the Alinity ci-series, which stacks reagent storage and sample processing areas, increases throughput without compromising space.



***As compared to ARCHITECT i2000 and ARCHITECT c8000.



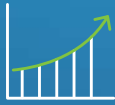
ALINITY CI-SERIES

FASTER. SIMPLER. SMARTER.

Simplify and streamline interactions with systems thoughtfully designed around the way you work.

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity**, **flexibility**, **operational productivity** and **confidence**.





CONFIDENCE

QUALITY ASSAY PERFORMANCE BUILT ON PROVEN TECHNOLOGY AND DESIGN

You face pressure every day to provide accurate and timely results. Our **broad menu** of differentiated assays delivers consistent, **commutable results** across platforms.

THE VALUE OF PROVEN TECHNOLOGY



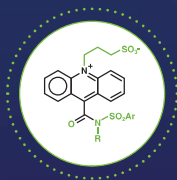
ICT Module

A single simple-to-install, integrated chip generates Na⁺, K⁺ and Cl⁻ results with CVs of 1% or less. Each module delivers 60,000 determinations, and maintenance is automated.



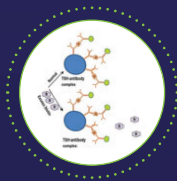
SmartWash Technology

SmartWash technology prevents clinically significant sample-to-sample carryover (≤ 0.1 ppm) and eliminates the need for additional consumables.



CHEMIFLEX

A refined chemiluminescence-detection technology with flexible assay protocols, combined with optimized assay design, provides enhanced assay performance.



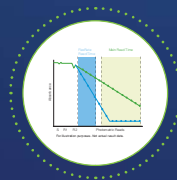
No Biotin Interference

Assays designed without streptavidin capture method. Ensures accuracy of results and timely analysis.



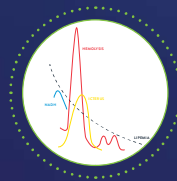
Clot and Bubble Detection

Sample pressure differential technology can detect bubbles, foam and clots to confirm sample integrity and aspiration accuracy.



FlexRate

FlexRate extends the linear ranges of enzyme assays for better first-time results and fewer repeats.



Sample Interference Indices

Measurement of hemolysis, icterus and lipemia levels reduces the risk of reporting incorrect results due to interference.

Alinity PRO

INFORMATICS*

CENTRALIZED MANAGEMENT ACROSS YOUR ALINITY SYSTEMS

Together with your Alinity systems, Alinity PRO is designed to fully maximize your systems' potential. Alinity PRO software works with Alinity systems to **enhance operational productivity** throughout your network, allowing for easier and consolidated system monitoring anytime, anywhere.

Consolidated Real-time Dashboards

- Remote dashboard capabilities enable staff to capitalize on system walkaway time via immediate notifications.

“Plan My Day” Checklists

- Forward-looking “Plan My Day” checklists help minimize planned downtime.

Real-time Mobile Notifications†

- Management of alert preferences is simplified through on/off toggle switches, allowing customization of what information staff receives to efficiently explore data and identify problems.



SHARE REAGENTS BETWEEN SYSTEMS AND REDUCE WASTE

- Reduce waste and inventory management by enabling staff to seamlessly transfer inventory between systems.



Alinity ci-series

YOUR PERSONALIZED SOLUTION — ALINITY

SIMPLIFYING DIAGNOSTICS AND REDEFINING LABORATORY PERFORMANCE

Achieve measurably better healthcare performance with **our personalized solutions**, consisting of our resourceful advocates, harmonized systems and intelligent insights.



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

The Alinity family of systems, including the Alinity ci-series, the Alinity m, the Alinity h-series, the Alinity s and the i-STAT Alinity, is for *in vitro* diagnostic use only. Not all products are available in all regions. This material is for use outside of the United States.

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Alinity



Alinity

ci-series

ALINITY | Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

HARMONIZED SYSTEMS

Clinical chemistry, immunoassay
and integrated systems to transform
your laboratory.

CHOOSE TRANSFORMATION

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY



Your vision. Our innovation. Designed for you, by you.*

Alinity is Abbott's next generation of systems, across key laboratory disciplines, designed to simplify diagnostics and help you deliver results that drive better patient outcomes. With Alinity, critical interactions between individuals, systems and information are streamlined, enabling you to redefine performance in your laboratory and your institution.



Alinity

Alignment | Innovation | Unity

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

Alinity. Your total lab solution, designed to deliver:*



UNIFORMITY

Standardize operations across your lab and network, and optimize your limited resources.

- User-driven design
- Intuitive user experience
- Easy-to-use graphic user interface



FLEXIBILITY

Adapt to day-to-day and long-term unpredictability of changing lab volumes.

- Scalable design
- Multiple track-connectivity options
- Open informatics and automation



OPERATIONAL PRODUCTIVITY

Address limited space and increasing demand with increased throughput and capacity.

- Maximized throughput in a compact footprint
- Increased sample and reagent load-up capacity
- Continuous reagent access



CONFIDENCE

Provide consistent high-quality service to physicians, and reduce waste.

- Error-proof design elements that safeguard against erroneous results
- High-quality assays with proven technology and design
- Assay harmonization to CLSI guidelines, ensuring clear performance parameter definitions



HARMONIZED SYSTEMS ACROSS ALL KEY LABORATORY DISCIPLINES

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

ALINITY CI-SERIES

Introducing clinical chemistry, immunoassay and integrated systems to transform your laboratory

The Alinity ci-series consists of compact, **scalable systems** to **maximize throughput** and **efficiency**, making today's high-performing laboratories run at their best, today and into the future.



Alinity c
Clinical Chemistry



Alinity ci-series
Integrated Clinical Chemistry
and Immunoassay



Alinity i
Immunoassay

KEY FEATURES



UNIFORMITY

COMMON USER EXPERIENCE

Standardize operations in your lab and across your network through common intuitive processes across systems.



FLEXIBILITY

SCALABLE SYSTEMS

Discover flexible solutions that help you adapt to the day-to-day and long-term unpredictability of changing lab volumes.



OPERATIONAL PRODUCTIVITY

MAXIMUM THROUGHPUT IN A SMALLER FOOTPRINT

Utilize your laboratory's space to its fullest potential with compact systems that provide more tests per square meter.



CONFIDENCE

QUALITY ASSAY PERFORMANCE

Have confidence in the results you deliver with proven technology and assay design.

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.



COMMON USER EXPERIENCE

Standardize operations across your laboratory and network.*

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.



USER-DRIVEN DESIGN

- Loading samples and reagents, prioritizing STATs, replacing solutions, and utilizing the user interface are just a few of the critical interactions that are consistent across systems.

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Alinity h-series

Hematology



Alinity s

Blood and Plasma
Screening

Alinity ci-series

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SCALABILITY AND MAXIMIZED THROUGHPUT

Realize the full potential of your existing resources, optimizing your performance, now and in the future.

In today's uncertain environment, labs need to be able to quickly adapt to daily changes, as well as plan for the long-term to ensure consistent delivery of services.

The **flexible and scalable** Alinity ci-series offers increased throughput and capacity, allowing you to easily add modules as your volume grows, without replacing your current systems. **Integrate up to four* modules** of multiple clinical chemistry and immunoassay combinations, all controlled by a single system control module.

Alinity ci-series INTEGRATE UP TO FOUR* MODULES IN VARYING COMBINATIONS.



PERFORM MORE TESTS PER SQUARE METER

Even when faced with limited space and resources, Alinity can more efficiently and effectively **process increased volumes** in a compact footprint.

Innovative engineering, combined with the Alinity ci-series **space-saving design**, which stacks reagent storage and sample processing areas, increases throughput without compromising space.

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.



QUALITY ASSAY PERFORMANCE

Greater confidence for your lab operations

You face pressure every day to provide accurate and timely results. Our **broad menu** of differentiated assays delivers consistent, **commutable results** across platforms that may improve clinical decision making and patient outcomes.

- Alinity ci-series assays are **harmonized** to Clinical and Laboratory Standards Institute (CLSI) guidelines, ensuring clear performance parameter definitions.

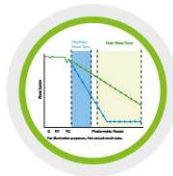


THE VALUE OF PROVEN TECHNOLOGY



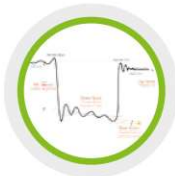
ICT MODULE

A single simple-to-install, integrated chip generates Na⁺, K⁺ and Cl⁻ results with CVs of 1% or less. Each module delivers 60,000 determinations, and maintenance is automated.



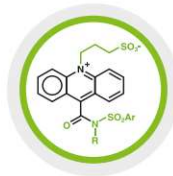
FLEXRATE

Extends the linear ranges of enzyme assays for better first-time results and fewer repeats.



CLOT AND BUBBLE DETECTION

Sample pressure differential technology can detect bubbles, foam, and clots to confirm sample integrity and aspiration accuracy.



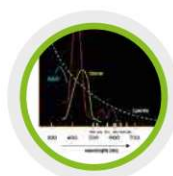
CHEMIFLEX

A refined chemiluminescence-detection technology with flexible assay protocols, combined with optimized assay design, provides enhanced assay performance.



SMARTWASH TECHNOLOGY

SmartWash technology prevents clinically significant sample-to-sample carryover (≤ 0.1 ppm) and eliminates the need for additional consumables.



SAMPLE INTERFERENCE INDICES

Measurement of hemolysis, icterus and lipemia levels reduces the risk of reporting incorrect results due to interference.

Alinity ci-series

ALINITY CI-SERIES

Faster. Simpler. Smarter.

Simplify and streamline interactions with systems thoughtfully designed around the way you work.



ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

ALINITY CI-SERIES

Thoughtfully designed around the way you work

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity, flexibility, operational productivity** and **confidence**.



SYSTEM SOFTWARE

Seamlessly work across systems with common, intuitive, easy-to-use software.



PRIORITY SAMPLE PROCESSING

Flexible options prioritize the most critical samples based on your workflow.



DEDICATED PRETREATMENT PATH

A dedicated pretreatment path allows continuous processing of routine and STAT immunoassays without compromise to turnaround times.



REAGENT AND SAMPLE MANAGER

Deliver samples, reagents and other solutions to any module with a single random-access robotic transport system without compromising STATs



CONTINUOUS ACCESS TO REAGENTS AND SUPPLIES

Continually load and unload supplies, no need to stop or pause the system. Load on the fly while the system continues to run.



ERROR-PROOF REAGENT LOADING

Prevent reagent mix-ups, retesting and probe crashes with built-in safeguards.



INCREASED LOAD-UP CAPACITY

Load up to 150 samples and up to 70 clinical chemistry or 47 immunoassay reagents per module.



ONBOARD CALIBRATORS AND CONTROLS

Load bar-coded calibrators and controls at any time, store them on the system, and automatically run them at user-defined intervals.



SYSTEM CONTROL MODULE

Control all modules of an integrated system from a single control unit

Alinity ci-series

INFORMATICS

Centralized management across your Alinity systems

Together with your Alinity systems, Alinity PRO is designed to fully maximize your systems' potential. Alinity PRO software works with Alinity systems to **enhance operational productivity** throughout your network, allowing for easier and consolidated system monitoring anytime, anywhere.

Designed with:

CONSOLIDATED REAL-TIME DASHBOARDS

- Remote dashboard capabilities enable staff to capitalize on system “walkaway time” via immediate notifications.

“PLAN MY DAY” – CHECKLISTS

- Forward-looking “Plan My Day” checklists help minimize interruptions.



Alinity PRO

DESIGNED TO SHARE REAGENTS BETWEEN SYSTEMS AND REDUCE WASTE.

- Reduce waste and inventory management by enabling staff to seamlessly transfer inventory between systems.



ABBOTT DIAGNOSTICS

Achieve measurably better healthcare performance with our personalized solutions.

We've reengineered our entire organization to support you and your changing needs, helping you achieve measurably better healthcare performance with our personalized solutions:



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

HARMONIZED SYSTEMS

A unified, holistic family of systems delivering unprecedented integration*



UNIFORMITY across the laboratory



FLEXIBILITY to adapt to a changing environment



OPERATIONAL PRODUCTIVITY to improve performance and workflow



CONFIDENCE in systems and performance



ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

YOUR PERSONALIZED SOLUTION

Choose tomorrow's approach today.
Alinity ci-series adapts to your laboratory's
needs, allowing you to achieve measurably
better healthcare performance.

Alinity

ci-series



CHOOSE TRANSFORMATION

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY

Alinity, Alinity ci-series, Alinity c, Alinity i, Alinity h-series, Alinity hs, Alinity hq, Alinity s, Alinity m, i-STAT Alinity, Alinity PRO, FlexRate, SmartWash, CHEMIFLEX and Choose Transformation are trademarks of Abbott Laboratories in various jurisdictions.





EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c Processing Module
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03R67-01	Alinity c Processing Module	56676	W0201010108
Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA		
Manufacturer SRN	US-MF-000017777		
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany		
Authorized Representative SRN	DE-AR-000009457		
Produced by (Site of Manufacture) (Name and Address)	Canon Medical Systems Corporation 1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan		
Conformity Assessment Procedure	Annex II and III		

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of 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, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Sr. Director, Instrument and Automation

Function: Quality

Signature: Thomas Creel

Date of Approval: 23-May-2022
Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive,
Irving, TX 75038

Date Issued: 23-May-2022

Supersedes: N/A

Full Name: Michele Smith-Waheed

Function: Associate Director, Regulatory Affairs

Signature: Michele Smith-Waheed

Date of Approval: 23-MAY-2022

Place Issued: Irving, Texas

Effective (Date or Lot Number): 23-May-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLAŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESESKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSESKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumbr ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštiteni naziv
HU	Kockázati osztály	Listaszám és készletkiszerezés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybos pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	EPH на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusi registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Όνομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Igaliotasis atstovas (pavadinimas ir adresas)	Igaliojojo atstovo unikalusi registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locuție producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformităţii	Anexa II şi III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviselőtől és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnăt pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatte	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatte	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Isigalioja (data arba partijos numeris)
NO	Ustedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställtigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of 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, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-ě) zdravotnický(-ě) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφωντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5 ^{ης} Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8 ^{ης} Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17 ^{ης} Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico <i>in vitro</i> descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico <i>in vitro</i> ; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud <i>in vitro</i> diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (<i>in vitro</i> diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustes. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic <i>in vitro</i> indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic <i>in vitro</i> , aux dispositions applicables de 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, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni <i>in vitro</i> dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o <i>in vitro</i> dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe áttettető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	We, the undersigned, hereby declare that the <i>in vitro</i> diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>In Vitro</i> Diagnostic Medical Devices; and additionally conforms applicable provisions of 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, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) <i>in vitro</i> sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici <i>in vitro</i>; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) <i>in vitro</i> diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par <i>in vitro</i> diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) <i>in vitro</i> diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl <i>in vitro</i> diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til <i>in vitro</i>-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til <i>in vitro</i>-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki <i>in vitro</i> spełnia(-ja) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki <i>in vitro</i>, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico <i>in vitro</i> descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico <i>in vitro</i>; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnatii, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic <i>in vitro</i> descrie mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul <i>in vitro</i>; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpisani, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) <i>in vitro</i> uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotníckych pomôckach <i>in vitro</i>; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för <i>in vitro</i>-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för <i>in vitro</i>-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen <i>in vitro</i> diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli <i>In Vitro</i> Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Prodicatorul	Reprezentant	Ordin	Data
				3R67					
DM000358080	ACCESORII ȘI INSTRUMENTE PENTRU ANALIZATOR	ALINITY	C PROCESSING MODULE	03R67-01	SUA	ABBOTT LABORATORIES	GBG-MLD S.R.L.	Rg04-000138	07-06-2022
DM000309806	ANALIZATOR BIOCHIMIC ȘI IMUNOLOGIC		Alinity c PROCESSING MODULE	03R6701	SUA	ABBOTT LABORATORIES	GBG-MLD S.R.L.	Rg04-000147	29-06-2021

Certificate of Registration

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This is to certify that:

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Irving
Texas
75038
USA

Holds Certificate Number:

FM 762425

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2019-12-18

Latest Revision Date: 2022-12-16

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

Page: 1 of 1



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Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-06-13

Latest Revision Date: 2022-12-12

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

Page: 1 of 1



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The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

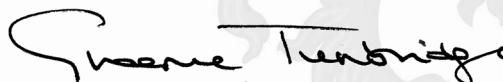
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-18

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

Page: 1 of 2



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Certificate No: **MDSAP 762409**

Registered Scope:

Design, Development, Manufacture, Refurbishment, and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. 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.



Original Registration Date: 2019-12-18

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

Page: 2 of 2

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Specificații tehnice dispozitiv medical automat biochimic, model Alinity c (ABBOTT/SUA)

Sistem complet automat, compact, pentru determinarea testelor de biochimie, cu tehnologie avansata, cu mai multe lungimi de unda de citire pentru a acoperi toate intervalele de testare.
Sistem deschis care permite configurarea de metode noi.
Sistemul permite dezvoltarea ulterioara prin conectarea la un sistem de imunologie sau la o linie de automatizare completa al laboratorului (biochimie, imunologie, hematologie si coagulare)
Capacitate de lucru: 1350 teste/ora
Principii de măsurare: fotometric, turbidimetric, potentiometric si teste calculate.
Capacitate de stocare a reactivilor, calibratorilor si controalelor in aparat, la temperatura 2-10 °C : 70 poziții cu refrigerare plus ISE (Na ⁺ , K ⁺ , Cl ⁻).
Sistemul permite incarcarea continua a reactivilor si consumabilelor fara a fi necesara trecerea instrumentului in pauza sau standby. De asemenea, sistemul permite indepartarea continua a deseurilor, fara a fi necesara trecerea instrumentului in pauza sau standby
Cuve de citire cu viata lunga de utilizare minim 1 an, cu spalare automata si verificarea fotometrica automata a puritatii fiecarei cuve, pentru toate lungimile de unda.
Tipuri de probe: ser, plasma, urina, LCR, sange integral si materii fecale. Sistemul semnalizeaza factorii de interferenta din proba (ser lipemic, icteric si hemolizat) fara a utiliza reactiv suplimentar.
Capacitate de incarcare totala de 150 probe in rack-uri care permit lucrul cu o varietate de tuburi : aliquot-uri, tuburi de 10-16 mm largime si pana la 100 mm inaltime, probe pediatrice, probe cu coduri de bara, fara sa necesite adaptoare
Pastrarea la bordul aparaturii in caruselul de refrigerarea a calibratorilor si a controalelor cu posibilitatea de programare automata a calibrarilor si protocoalelor de rulare a controalelor la anumite intervale de timp, fara interventia/ prezenta operatorului
Sistemul are capacitatea de a procesa probe in regim de urgenta, permitand mai multe cai de prioritizare: individuala a probei sau prin configurare de pozitii fixe de incarcare probe STAT.
Retestare automata, dilutie automata, testare complementara (test reflex).
Alinity c utilizeaza reactivi lichizi, gata de utilizare, (pentru a evita erorile de reconstituire), cu liniaritati mari, marcati cu cod de bare bidimensional.
Sistemul ne necesita virfuri de unica folosinta. Alinity c are tehnologia SmartWash Technology .
Detector de cheaguri, senzor de bule de aer si spuma, de obstacole; detectie nivel de proba pentru fiecare unitate de pipetare- ac de reactiv si ac de proba.
Modulul de ioni (Na ⁺ ,K ⁺ ,Cl ⁻) – este incorporat in modulul de biochimie, cu mentenanta automata, fara a necesita calibrare continua, cu aplicatii pentru ser, plasma, urina, cu o capacitate de testare de 60 000 determinari/modul .

Liniaritate extinsa pentru enzime
Inventarierea permanenta a reactivilor, consumabilelor si reziduurilor prin intermediul softului.
Control de calitate incorporat, cu posibilitate de accesare in orice moment (graficele Levey Jennings, calculul DS, CV).
Software-ul posedat, pe langa metodele standard stocate, pozitii deschise pentru programarea a noi aplicatii sau protocoale de lucru
Posibilitate arhivare electronica pentru rezultate, controale, calibrari, back-up.
Posibilitate de stocare a 200.000 de rezultate de pacienti pe unitatea de stocare interna a sistemului
Posibilitate de inregistrare a etapelor de intretinere a analizorului (prin software, cu posibilitate de printare)
Interfata informationala bidirectionala, cu posibilitatea de legare la reseaua informatica a laboratorului
Monitorizare permanenta a statusului testelor si a probelor in lista de lucru.
Posibilitate printare rezultate per pacient sau per total
Posibilitatea de monitorizare si diagnoza la distanta (prin Internet) cu posibilitatea de configurari si interventii tehnice preventive si proactive garantand functionarea continua a aparatului.
Posibilitate de instalare de soft ce permite optimizarea consumului de reactiv prin transferul acestora intre diferite sisteme similare, asigurand si trasabilitatea lor.
Aparatul se va livra cu toate accesoriile necesare (UPS, statie de apa)
Sistemul, cu toate subansamblele: modul procesare, modul ISE, modul incarcare probe, este un sistem compact, care ocupa un spatiu cat mai mic, conform cerintelor laboratorului, incadrandu-se intr-o suprafata dreptunghiulara cu dimensiunile de 134 cm (lungime) x 117 cm (latime)
Consum maxim de apa 30 l/ora
Mentenananta sistemului poate fi facuta automat.
Livrarea aparatului se va efectua in termen de 60 zile din data semnarii contractului de achizitie.



CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Daniel Gutu

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ALINITY CI Service Training

February 19th – March 3rd, 2018

Hector Gutierrez/Federico Dori

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

02.03.2018

DATE DD.MM.YYYY

Germany - Delkenheim

Abbott