Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074MPH0173S4
Basic UDI-DI Name: CELL-DYN Sapphire and CELL-DYN Ruby Systems Diluent/Sheath
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
01H73-01	CELL-DYN Sapphire and CELL-DYN Ruby Systems Diluent/Sheath	58237	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
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)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
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. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan
Function: Site QA, Director Quality Assurance
Signature: Cheryl Nowlan
Date of Approval: 28 MAR 2023

Full Name: Katie Bessette
Function: Director Regulatory Affairs
Signature: Katie Bessett
Date of Approval: 28-MAR-2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023
Supersedes: Oct 11, 2022

Place Issued: Santa Clara, CA USA
Effective (Date or Lot Number): MAR 28 2023

Digitally signed by Ceaicovschi Tudor
Date: 2025.01.17 09:22:39 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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 PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	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	Katalooginumber 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 zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-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 prekybinis 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 şi cod dimensiune	Denumirea produsului şi 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)	ЕРН 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 unikalusis 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)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)	Procedură de evaluare a conformității
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II şi III	Numele complet
SK	Príloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	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 képviseletében 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	Funcţia	Semnat pentru şi 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	Erstatter	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	Erstatter	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	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	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	Verkställigt (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. This declaration is made in accordance with Annex IV of the IVD Regulation 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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) 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. Toto prohlášení je v souladu s Přílohou IV nařízení IVD 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, 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 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD 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 *in vitro* 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 *in vitro*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* 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 *in vitro*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* 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 *in vitro*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-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 *in vitro*-diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* 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 *in vitro*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise 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 in vitro. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-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 *in vitro*-diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of form

Abbott

Declaration of Conformity

Certificate Identification: SC-08H59

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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

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

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

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

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0380WZ
Basic UDI-DI Name: CELL-DYN Ruby CN-FREE HGB/NOC LYSE
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03H80-02	CELL-DYN Ruby CN-FREE HGB/NOC LYSE	61165	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
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)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
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. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan
Function: Site QA, Director Quality Assurance
Signature: Cheryl Nowlan
Date of Approval: 19 APR 2023

Full Name: Katie Bessette
Function: Director Regulatory Affairs
Signature: Katie Bessett
Date of Approval: 19-APR-2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: APR 19 2023
Supersedes: March 28, 2023

Place Issued: Santa Clara, CA USA
Effective (Date or Lot Number): APR 19 2023

Abbott

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 PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	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	Katalooginumber 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 zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-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 prekybinis 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

Abbott

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН 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 (Ονομα 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 unikalusis 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

Abbott

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jedinė registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)	Procedură de evaluare a conformităţii
SK	Autorizovaný zástupca (názov a adresa)	Jedinė registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

Abbott

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II şi III	Numele complet
SK	Príloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	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 képviseletében 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	Funcţia	Semnat pentru şi 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

Abbott

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	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	Erstatter	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	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	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	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

Abbott

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. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че горесписаното(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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) 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. Toto prohlášení je v souladu s Přílohou IV nařízení IVD 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, 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 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD 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 *in vitro* 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 *in vitro*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* 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 *in vitro*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* 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 *in vitro*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-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 *in vitro*-diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* 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 *in vitro*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise 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 in vitro. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-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 *in vitro*-diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0852XM
Basic UDI-DI Name: CELL-DYN Ruby WBC Lyse
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08H52-01	CELL-DYN Ruby WBC Lyse	61165	W0103010105

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
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)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
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. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan
Function: Site QA, Director Quality Assurance
Signature: Cheryl Nowlan
Date of Approval: 28 MAR 2023

Full Name: Katie Bessette
Function: Director Regulatory Affairs
Signature: Kat Bessett
Date of Approval: 28-MAR-2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023
Supersedes: Oct 11, 2022

Place Issued: Santa Clara, CA USA
Effective (Date or Lot Number): MAR 28 2023

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 PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	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	Katalooginumber 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 zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-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 prekybinis 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 şi cod dimensiune	Denumirea produsului şi 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)	ЕРН 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 unikalusis 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)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)	Procedură de evaluare a conformității
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II şi III	Numele complet
SK	Príloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	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 képviseletében 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	Funcţia	Semnat pentru şi 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	Erstatter	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	Erstatter	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	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	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	Verkställigt (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. This declaration is made in accordance with Annex IV of the IVD Regulation 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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) 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. Toto prohlášení je v souladu s Přílohou IV nařízení IVD 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, 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 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD 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 *in vitro* 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 *in vitro*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* 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 *in vitro*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* 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 *in vitro*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-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 *in vitro*-diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* 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 *in vitro*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise 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 in vitro. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-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 *in vitro*-diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of form

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

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

DICHIARAZIONE DI CONFORMITA' CE

CE *DECLARATION OF CONFORMITY*

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

DICHIARA
DECLARES

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

CONTENITORI PER CAMPIONI BIOLOGICI

SPECIMEN CONTAINERS

PRODOTTI NON STERILI – *NOT STERILE PRODUCTS*

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

> **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27Th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.

> **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.

> **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato */ Released*
Canelli, 26.07.2015

Duilio BUONO
Responsabile Assicurazione Qualità

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
1011	Contenitori per feci 18ml, PS, con tappo a pressione con paletta	*Faeces containers 18ml, PS, with pressure cap and spoon*
1011/E	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1011/E/50	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta, in confezioni da 50 pezzi	*Faeces containers 18ml, PS, with pressure cap and spoon, with label, in bags of 50 pieces*
1011/E/AST	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1012	Contenitori per campioni biologici 18ml, PS, con tappo a pressione	*Specimen containers 18ml, PS, with pressure cap*
1013	Contenitori da 18ml, PS, senza tappo	*Containers 18ml, PS, without cap*
1030	Contenitori per urine 130ml, PS, graduati, tappo a pressione	*Graduated urine containers 130ml, PS, pressure cap*
1030/E	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 130ml, PS, pressure cap, with label*
1030/E/CS	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta, confezione singola	*Graduated urine containers 130ml, PS, pressure cap, with label, individually wrapped*
1030/MO	Contenitori per urine 130ml, PP, graduati, tappo a pressione	*Graduated urine containers 130ml, PP, pressure cap*
1030/MO/E	Contenitori urina 130ml, in PP tappo a pressione, graduati, etichetta	*Graduated urine containers 130ml, PP, pressure cap, label*
1030/MO/T	Contenitori urina 130ml, in PP tappo a pressione inserito, graduati	*Graduated urine containers 130ml, PP, pressure cap*
1030/R	Contenitori per urine 130ml, PS, graduati, tappo a pressione rosso	*Graduated urine containers 130ml, PS, red pressure cap*
1030/S	Contenitori per urine 130ml, PS, graduati, senza tappo	*Graduated urine containers 130ml, PS, without cap*
1030/T	Contenitori per urine 130ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 130ml, PS, with inserted pressure cap*
1040	Contenitori per urina 120ml, PP, con coperchio autoadesivo	*Graduated urine containers 120ml, PP, with self-adhesive cap*
1040/P	Contenitori per urina 120ml, PS, con coperchio autoadesivo	*Graduated urine containers 120ml, PS, with self-adhesive cap*
1040/P/S	Contenitori per urina 120ml, PS, senza coperchio autoadesivo	*Graduated urine containers 120ml, PS, without self-adhesive cap*
1040/S	Contenitori per urina 120ml, PP, senza coperchio autoadesivo	*Graduated urine containers 120ml, PP, without self-adhesive cap*
1041	Contenitori per campioni biologici 30ml, PS, con tappo a pressione	*Specimen containers 30ml, PS, with pressure cap*
1041/E	Contenitori per campioni biologici 30ml, PS, con tappo a pressione, con etichetta	*Specimen containers 30ml, PS, with pressure cap, with label*
1041/S	Contenitori per campioni biologici 30ml, PS, senza tappo	*Specimen containers 30ml, PS, without cap*
1041/T	Contenitori per campioni biologici 30ml, PS, con tappo a pressione inserito	*Specimen containers 30ml, PS, with inserted pressure cap*
1050	Contenitori per urine 150ml, PS, graduati, tappo a pressione	*Graduated urine containers 150ml, PS, pressure cap*
1050/E	Contenitori per urine 150ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 150ml, PS, pressure cap, with label*
1050/S	Contenitori per urine 150ml, PS, graduati, senza tappo	*Graduated urine containers 150ml, PS, without cap*
1050/T	Contenitori per urine 150ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 150ml, PS, with inserted pressure cap*
1051	Contenitori per espettorato 60ml, PS, con tappo a pressione	*Sputum containers 60ml, PS, with pressure cap*
1051/E	Contenitori per espettorato 60ml, PS, con tappo a pressione, con etichetta	*Sputum containers 60ml, PS, with pressure cap, with label*
1051/S	Contenitori per espettorato 60ml, PS, senza tappo a pressione	*Sputum containers 60ml, PS, without pressure cap*
1051/S/CS	Contenitori per espettorato 60ml, PS, senza tappo a pressione, in confezione singola	*Sputum containers 60ml, PS, without pressure cap, individually wrapped*
1051/T	Contenitori per espettorato 60ml, PS, con tappo a pressione inserito	*Sputum containers 60ml, PS, with inserted pressure cap*
1061	Contenitori per campioni biologici 35ml, PS, con tappo a pressione	*Specimen containers 35ml, PS, with pressure cap*
10621	Contenitori rotondi "SECURBOX" da 2.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 10 fori. Con manico	*Disposable container"SECURBOX"2,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 10 holes. With handle*
10622	Contenitori rettangolari "SECURBOX" da 5.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 99 fori. Con manico	*Disposable container"SECURBOX"5,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 99 holes. With handle*
10631	Contenitori da 5ml, PE, tappo a vite	*Containers 5ml, PE, screw cap*
10632	Contenitori da 30ml, PE, tappo a vite	*Containers 30ml, PE, screw cap*
10633	Contenitori da 90ml, PE, tappo a vite	*Containers 90ml, PE, screw cap*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
1070	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap*
1070/E	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite, con etichetta	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap, with label*
1081	Contenitori per urine 150ml, PS, graduati, tappo a vite	*Graduated urine containers 150ml, PS, screw cap*
1081/CS	Contenitori per urine 150ml, PS, graduati, tappo a vite, in confezione singola	*Graduated urine containers 150ml, PS, screw cap, individually wrapped*
1081/E	Contenitori per urine 150ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PS, screw cap, with label*
1081/T	Contenitori urina 150ml, in PS con tappo a vite inserito,	*Graduated urine containers 150ml, PS, screw cap*
1211	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1211/CS	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1212	Contenitori per campioni biologici 60ml, PS, con tappo a pressione	*Specimen containers 60ml, PS, with pressure cap*
1212/CS	Contenitori per campioni biologici 60ml, PS, con tappo a pressione, confezione singola	*Specimen containers 60ml, PS, with pressure cap, individually wrapped*
1213	Contenitori da 60ml, PS, senza tappo	*Containers 60ml, PS, without cap*
1230	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/10	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/100	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/CS	Contenitori per urine 200ml, PS, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PS, screw cap, ind. wrapped*
1230/E	Contenitori per urine 200ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PS, screw cap, with label*
1230/S/E	Contenitori urina 200ml, in PS senza tappo, graduati,	*Graduated urine containers 200ml, PS, with label*
1230/T	Contenitori urina 200ml, in PS tappo a vite inserito,	*Graduated urine containers 200ml, PS, with inserted screw cap*
1230/TE	Contenitori per urine 200ml, PS, graduati, tappo a vite inserito, con etichetta	*Graduated urine containers 200ml, PS, with inserted screw cap, with label*
12731	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
12731/E	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
12731/SAC	Taniche in PE da 2.500ml per la raccolta urine 24ore,	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, individually wrapped*
12731K	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
14120	Contenitori per istologia da 20ml, in PP, tappo a vite verde	*20 ml Surgical specimen containers in PP, with yellow screw cap*
14120/B	Contenitori per istologia da 20ml, in PP, tappo a vite giallo, etichetta biohazard	*20 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14121	Contenitori per istologia da 40ml, in PP, tappo a vite giallo	*40 ml Surgical specimen containers in PP, with yellow screw cap*
14121/B	Contenitori per istologia da 40ml, in PP, tappo a vite giallo, etichetta biohazard	*40 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14122	Contenitori per istologia da 60ml, in PP, tappo a vite giallo	*60 ml Surgical specimen containers in PP, with yellow screw cap*
14122/B	Contenitori per istologia da 60ml, in PP, tappo a vite giallo, etichetta biohazard	*60 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14123	Contenitori per istologia da 90ml, in PP, tappo a vite giallo	*90 ml Surgical specimen containers in PP, with yellow screw cap*
14123/B	Contenitori per istologia da 90ml, in PP, tappo a vite giallo, etichetta biohazard	*90 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14124	Contenitori per istologia da 120ml, in PP, tappo a vite giallo	*120 ml Surgical specimen containers in PP, with yellow screw cap*
14124/B	Contenitori per istologia da 120ml, in PP, tappo a vite giallo, etichetta biohazard	*120 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14131	Contenitori per biopsie in PS, con tappo a pressione in PE, da 30ml	*Biopsy specimen containers in PS with pressure cap in PE, 30 ml*
14132	Contenitori per biopsie in PS, con tappo a pressione in PE, da 50ml	*Biopsy specimen containers in PS with pressure cap in PE, 50 ml*
14134	Contenitori per biopsie in PS, con tappo a pressione in PE, da 100ml	*Biopsy specimen containers in PS with pressure cap in PE, 100 ml*
14136	Contenitori per biopsie in PS, con tappo a pressione in PE, da 150ml	*Biopsy specimen containers in PS with pressure cap in PE, 150 ml*
14138	Contenitori per biopsie in PS, con tappo a pressione in PE, da 200ml	*Biopsy specimen containers in PS with pressure cap in PE, 200 ml*
14140	Contenitori per biopsie in PS, con tappo a pressione in PE, da 250ml	*Biopsy specimen containers in PS with pressure cap in PE, 250 ml*
14142	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
14142/B	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap, Biohazard label*
14143	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap*
14143/B	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap, Biohazard label*
14144	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap*
14144/B	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap, Biohazard label*
14150	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione	*Surgical specimens transparent containers 150ml, PP, with pressure cap*
14150/B	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 150ml, PP, with pressure cap, Biohazard label*
14151	Contenitori per istologia da 250ml, in PP, tappo a vite giallo	*250 ml Surgical specimen containers in PP, with yellow screw cap*
14151/B	Contenitori per istologia da 250ml, in PP, tappo a vite giallo, etichetta biohazard	*250 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14152	Contenitori per istologia da 500ml, in PP, tappo a vite giallo	*500 ml Surgical specimen containers in PP, with yellow screw cap*
14152/B	Contenitori per istologia da 500ml, in PP, tappo a vite giallo, etichetta biohazard	*500 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14153	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo	*1000 ml Surgical specimen containers in PP, with yellow screw cap*
14153/B	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo, etichetta biohazard	*1000 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14155	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione	*Surgical specimens transparent containers 250ml, PP, with pressure cap*
14155/B	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 250ml, PP, with pressure cap, Biohazard label*
14160	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione	*Surgical specimens transparent containers 500ml, PP, with pressure cap*
14160/S	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 500ml, PP, with pressure cap, serigraphed*
14170	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap*
14170/S	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap, serigraphed*
14175	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap*
14175/B	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap, Biohazard label*
14175/T	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione inserito	*Surgical specimens transparent containers 2.000ml, PP, with inserted pressure cap*
14180	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap*
14180/B	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, Biohazard label*
14180/S	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, serigraphed*
14185	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap*
14185/B	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap, Biohazard label*
14190	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione	*Big surgical specimens containers 5.600ml, PP, with pressure cap*
14190/B	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 5.600ml, PP, with pressure cap, biohazard label*
14192	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione	*Big surgical specimens containers 2,500ml, PP, with pressure cap*
14192/B	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 2,500ml, PP, with pressure cap, biohazard label*
14195	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione	*Big surgical specimens containers 11.000ml, PP, with pressure cap*
14195/B	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 11.000ml, PP, with pressure cap, biohazard label*
1560	Contenitori per saliva 30 ml, in PP, tappo a vite,	*Autoclavable sputum collection container 30 ml, in PP, screw cap*
1630	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
1630/E	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
19550	Contenitore per la raccolta delle urine per test antidoping	*Urine containers for testing drugs abuse*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
2030	Contenitori per campioni biologici 30ml, PP, tappo a vite	*Specimen containers 30ml, PP, with screw cap*
2030/E	Contenitori per campioni biologici 30ml, PP, tappo a vite, etichetta	*Specimen containers 30ml, PP, with screw cap, label*
2030/P	Contenitori per campioni biologici 30ml, PP, tappo a vite rosso non inserito	*Specimen containers 30ml, PP, with red screw cap not inserted*
2030/S	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte	*Specimen containers 30ml, PP, with screw cap in separate bag*
2030/S/R	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte rosso	*Specimen containers 30ml, PP, with red screw cap in separate bag*
2040	Contenitori per campioni biologici 60ml, PS, tappo a vite	*Specimen containers 60ml, PS, with screw cap*
2040/B	Contenitori per campioni biologici 60ml, PS, tappo a vite bianco	*Specimen containers 60ml, PS, with white screw cap*
2040/E	Contenitori per campioni biologici 60ml, PS, tappo a vite, con etichetta	*Specimen containers 60ml, PS, with screw cap, with label*
2040/E/R	Contenitori campioni biologici 60ml, PS, tappo inserito rosso	*Specimen containers 60ml, PS, with screw cap, with label*
2040/P	Contenitori campioni biologici 60ml, in PS, Ø35 x 70 mm,	*Specimen containers 60ml, PS, with screw cap*
2040/P/E	Contenitori campioni biologici 60ml, PS, Ø35x70mm, etichetta,	*Specimen containers 60ml, PS, with screw cap, with label*
2040/R	Contenitori per campioni biologici 60ml, PS, tappo a vite rosso	*Specimen containers 60ml, PS, with red screw cap*
2042	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta	*Specimen containers 60ml, PS, with screw cap and spoon*
2042/E	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta, con etichetta	*Specimen containers 60ml, PS, with screw cap and spoon, with label*
2050	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/100	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/B	Contenitori di colore blu per campioni biologici 60ml, PP, tappo a vite	*Specimen containers blue colour 60ml, PP, with screw cap*
2050/C	Tappi a vite colore giallo per contenitori cod. 2050	*Yellow screw cap for containers cod 2050*
2050/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2050/DDK	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito rosso	*Specimen containers 60ml, PP, with red inserted screw cap*
2050/E	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 60ml, PP, with inserted screw cap, with label*
2050/E/S	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito, con etichetta	*Specimen containers 60ml, PP, with screw cap not inserted, with label*
2050/P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/P/E	Contenitori campioni biologici 60ml, PP, Ø35x70mm, graduati,	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/PR	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito colore rosso	*Specimen containers 60ml, PP, with screw cap not inserted red colour*
2050/R	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito colore rosso	*Specimen containers 60ml, PP, with screw cap inserted red colour*
2050/S	Contenitori per campioni biologici 60ml, PP, senza tappo	*Specimen containers 60ml, PP, without cap*
2050/T	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito	*Specimen containers 60ml, PP, with inserted screw cap*
2050/TAPPO/B	Tappi a vite colore blu per contenitori cod. 2050	*Blue screw cap for containers cod 2050*
2050P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2052	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/10	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/100	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, individually wrapped*
2052/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2052/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2052/R	Contenitori per feci 60ml, PP, con tappo a vite rosso con paletta	*Faeces containers 60ml, PP, with red screw cap and spoon*
2052/T5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2062	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/10	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/E	Contenitori per feci da 60ml, in PP, tappo vite con paletta, etichetta	*Faeces containers in PP 60ml, screw cap, with label*
2062/P	Contenitori per feci da 60 ml, in PP, tappo a vite a parte	*Faeces containers in PP 60ml, not assembled screw cap*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
2072	Contenitori per feci da 60 ml, in PS, tappo a vite	*Faeces containers in PS 60ml, screw cap*
2072/E	Contenitori per feci da 60ml, in PS, tappo vite con paletta, etichetta	*Faeces containers in PS 60ml, screw cap, with label*
2072/P	Contenitori per feci da 60 ml, in PS, tappo a vite a parte	*Faeces containers in PS 60ml, not assembled screw cap*
2120	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/100	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/50	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/B	Contenitori per urine 150ml, PP, graduati, tappo a vite bianco	*Graduated urine containers 150ml, PP, white screw cap*
2120/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/M	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/MI	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/E	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PP, screw cap, with label*
2120/E/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici, con etichetta	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic, with label*
2120/ES	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta non applicata	*Graduated urine containers 150ml, PP, screw cap, with label in separate bag*
2120/N	Contenitori per urine 150ml, PP, graduati, tappo a vite neutro	*Graduated urine containers 150ml, PP, neutral screw cap*
2120/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 150ml, PP, red screw cap*
2120/S	Contenitori per urine 150ml, PP, graduati, senza tappo	*Graduated urine containers 150ml, PP, without cap*
2120/T	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T/100	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 100 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 100 pcs*
2120/T/N	Contenitore urina 150ml, in PP tappo a vite neutro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T5	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 5 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 5 pcs*
2120/T50	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 50 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 50 pcs*
2120/TB	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito bianco	*Graduated urine containers 150ml, PP, with inserted white screw cap*
2120/TB	Contenitori urina 150ml, in PP con tappo a vite bianco	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TE	Contenitori urina 150ml, in PP tappo vite azzurro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TN	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito di colore neutro	*Graduated urine containers 150ml, PP, with inserted screw cap neutral colour*
2120/TR	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito colore rosso	*Graduated urine containers 150ml, PP, with red inserted screw cap*
2120/V/500	Contenitori per urine 150ml, PP, graduati, tappo a vite verde	*Graduated urine containers 150ml, PP, screw cap green colour*
2220	Contenitori per urine 200ml, PP, graduati, tappo a vite	*Graduated urine containers 200ml, PP, screw cap*
2220/250	Contenitori urina 200ml, in PP tappo a vite, graduati,	*Graduated urine containers 200ml, PP, screw cap*
2220/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped*
2220/E	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PP, screw cap, with label*
2220/E/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta, confezione singola	*Graduated urine containers 200ml, PP, screw cap, with label, individually wrapped*
2220/R	Contenitori per urine 200ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 200ml, PP, red screw cap*
2220/S	Contenitori per urine 200ml, PP, graduati, senza tappo a vite	*Graduated urine containers 200ml, PP, without screw cap*
2220/T	Contenitori per urine 200ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 200ml, PP, with inserted screw cap*
2250	Contenitori campioni biologici da 40 ml, in PP	*Specimen containers 40 ml, in PP*
2420	Contenitori per urine 150ml, PP, graduati, tappo a vite e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, screw cap and plug*
2420/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, with screw cap and plug red colour*
2420/TR	Contenitori urine 150ml, PP, graduati, tappo a vite rosso e tappino prelievo campioni inserito	*Graduated urine containers 150ml, PP, with inserted screw cap and plug red colour*
2440	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm.	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
2440/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, individually wrapped*
2440/E	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label*
2440/E/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label, individually wrapped*
2440/P	Contenitori campioni biologici 60ml, PS, con tappo a parte,	*Specimen containers in PS with screw cap, 60 ml, Ø 38 x 65 mm*
2442	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2442/E	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm, con etichetta.	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm, with label*
2442/R	Contenitori per feci in PS con tappo a vite rosso e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with red screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2450	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2450/B	Contenitori per campioni biologici 60ml, PP, tappo a vite bianco	*Specimen containers 60ml, PP, with white screw cap*
2450/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2450/E	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	*Specimen containers 60ml, PP, with screw cap, with label*
2450/P	Contenitori campioni biologici 60ml, in PP, Ø38 x 65 mm,	*Specimen containers 60ml, PP, with screw cap, with label*
2450/R	Contenitori per campioni biologici 60ml, PP, tappo a vite colore rosso	*Specimen containers 60ml, PP, with red screw cap*
2452	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2452/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2452/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2452/R	Contenitori per feci 60ml, PP, con tappo a vite rosso e con paletta	*Faeces containers 60ml, PP, with red screw cap and with spoon*
2452/T/5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2580	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, with screw cap*
2580/B	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco	*Specimen containers 25ml, PS, with white screw cap*
2580/E	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/E/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, confezione singola	*Specimen containers 25ml, PS, with screw cap, with label, individually wrapped*
2580/E/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/P/W	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/EB	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PS, with screw cap, with white label*
2580/ER	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with not inserted screw cap, with label*
2580/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/PB	Contenitori campioni biologici 25ml, in PS, Ø25 x 90 mm,	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/S	Contenitori per campioni biologici 25ml, PS, senza tappo	*Specimen containers 25ml, PS, without cap*
2580/TAPPO/A	Tappo a vite colore azzurro per contenitori cod. 2580/2680	*Light blue screw cap for containers cod. 2580/2680*
2580/TBIANCO	Tappo a vite colore bianco per contenitori cod. 2580/2680	*White screw cap for containers cod. 2580/2680*
2580/W	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco non inserito	*Specimen containers 25ml, PS, with white not inserted screw cap*
2580P	Contenitori campioni biologici 25ml, PS, con tappo a vite	*Specimen containers 25ml, PS, with white not inserted screw cap*
2588	Contenitori per feci 25ml, PS, con tappo a vite con paletta	*Faeces containers 25ml, PS, with screw cap and spoon*
2588/E	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, with screw cap and spoon, with label*
2588/E/CS	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 25ml, PS, with screw cap and spoon, with label, individually wrapped*
2588/EB	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta bianca	*Faeces containers 25ml, PS, with screw cap and spoon, with white label*
2588/P	Contenitori per feci 25ml, PS, con tappo a vite con paletta a parte	*Faeces containers 25ml, PS, with screw cap and spoon in separate bag*
2588P	Paletta in polipropilene bianco	*Spoon in white polypropylene*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

COD.	DESCRIZIONE	*DESCRIPTION*
2640	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
2640/E	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
2680	Contenitori per campioni biologici 25ml, PP, tappo a vite	*Specimen containers 25ml, PP, with screw cap*
2680/E	Contenitori per campioni biologici 25ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 25ml, PP, with inserted screw cap, with label*
2680/P	Contenitori per campioni biologici 25ml, PP, tappo a vite non inserito	*Specimen containers 25ml, PP, with not inserted screw cap*
2680/S	Contenitori per campioni biologici 25ml, PP, senza tappo a vite	*Specimen containers 25ml, PP, without screw cap*
2688	Contenitori per feci 25ml, PP, con tappo a vite con paletta	*Faeces containers 25ml, PP, with screw cap and spoon*
2688/E	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PP, with screw cap and spoon, with label*
2688/E/CS	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta, in confezione singola	*Faeces containers 25ml, PP, with screw cap and spoon, with label, individually wrapped*
5024	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5024/E	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
5024/F	"24 ore" da 2.500 ml tipo bottiglia in pe	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap*
5024K	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5050/S	Contenitori per feci da 60ml, in PP, senza tappo	*Faeces containers in PP 60ml, without cap*
5120	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto.	*120 ml urine containers in PP, with screw cap with device for vacuum tube*
5120/CS	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, confezione singola	*120 ml urine containers in PP, with screw cap with device for vacuum tube, individually wrapped*
5434	Contenitori per la raccolta delle urine nelle 24 ore, 2.000ml, PE, tappo a vite, graduata	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap*
5434/M	Contenitori per la raccolta delle urine nelle 24 ore, 2000ml, PE, tappo vite, graduata, marrone	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap, brown*
5471	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes.*
5472	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes.*
5671	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5672	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5731	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes*
5732	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
6840	Contenitore per trasporto campioni con coperchio ermetico	*Test tubes securbox with hermetic lid*

Duilio BUONO
Responsabile Assicurazione Qualità

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da

implemented by

APTACA S.p.A.

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

nella Sede Operativa di

Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma

is in compliance with the standard

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

per i seguenti Processi

concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

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

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

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HAV IgM** CODE: **AVM.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – SEPTEMBER 2003
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg Germany
PRODUCT/ MODEL:	Hematology Analyzer/ H60, H60S, H66, H66S, H68, H68S, H69, H69S Reagents for Hematology Analyzer/ HD600 Diluent, HL600 Lyse, HC600 Cleaner, ED-60D Control H, ED-60D Control N, ED-60D Control L Hematology Controls, ED-CAL PLUS Hematology Calibrator.

The accessories are used together with the product.

EDMA[Name/Code]: CC Hardware + accessories + consumables + software/23.01.10.01.00
CBC-Reagents(Cleaning-/Diluting-/Lysing-/Sheat-fluids)/13.01.01.01.00
Blood Multilevel Controls/ 13.01.50.03.00
Whole Blood Calibrators/ 13.01.50.07.00

CLASSIFICATION:General/other device, devices other than those covered by Annex II and devices for performance evaluation, non-self-testing, according to article 9 of IVDD.

CONFORMITY ASSESSMENT ROUTE: Annex III

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: **EN ISO 14971: 2012, IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN 62304:2006 +A1:2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002，EN ISO 17511:2003, EN ISO 23640:2015**

CE MARK: CE

START OF CE-MARKING: 2021. 8. 10

PLACE, DATE OF ISSUE: SHENZHEN, 2021.8.10

SIGNATURE:

NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

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

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

TÜV SÜD Product Service

Certificate

No. Q5 091264 0016 Rev. 04

Holder of Certificate: **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls, External electronic simulator, capillary adaptor, Ampoule adaptor), Hematology analyzer; Reagents for Hematology Analyzer (including diluent, lyse, cleaner, bleach, hematology control, hematology calibrator), Video Colposcope, Ultrasonic Transducer, TOCO Transducer, SPO2 Sensor, Temperature Probe, ECG Cable, Telemetry Transmitter, NIBP Cuff, Specific Protein Immunoassay System (including Protein Assay kit, Assay buffer, Sample dilution buffer, Washing buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation sensor, Ambulatory Blood Pressure Monitor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket, ECG analysis software, Fetal Telemetry System, Holter ECG and ABP System, Blood Sampler, Molecular Diagnostic System (including Molecular Diagnostic Analyzer, Test Kit, Sample Collection Tube), Colloidal Gold Immunosassay Analyzer, Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 091264 0016 Rev. 04

Report No.: BJ22089104
Valid from: 2023-06-26
Valid until: 2025-11-30

Date, 2023-06-26

Christoph Dicks
Head of Certification/Notified Body

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

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

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

TÜV SÜD Product Service

Certificate

No. Q5 091264 0016 Rev. 04

Applied Standard(s):

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

Facility(ies):

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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

TÜV®

Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

Helena Biosciences Europe,
Gateshead, Tyne and Wear,
NE11 0SD, United Kingdom
Tel +44 (0)191 482 8440
info@helena-biosciences.com
www.helena-biosciences.com

EC REP
Prince Technologies B.V.
Waanderweg 62,
7812 HZ Emmen,
The Netherlands

Declaration of Conformity

HL-7- 0511 DC DOI 2013/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

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

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Effective Date: 2024-04-14
Latest Revision Date: 2024-03-26
Expiry Date: 2027-04-13

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.