



EU Declaration of Conformity

Basic UDI-DI: 038074ARK0762NC
Basic UDI-DI Name: ARCHITECT TSH
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7K62-25 7K62-30 7K62-35	ARCHITECT TSH Reagent Kit	54386	W01020410
7K62-01	ARCHITECT TSH Calibrators	38272	W0102152202
7K62-10	ARCHITECT TSH Controls	38271	W0102152002

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland		
Manufacturer SRN	IE-MF-000010070		
Authorized Representative (Name and Address)	N/A		
Authorized Representative SRN	N/A		
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland		
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123		
Conformity Assessment Procedure	Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	EU Certificate No. No. V12 054869 0013	
	Common Specifications (CS)		

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: David Spellman	Full Name: Sandra Gallagher
Function: Director Quality Assurance/Site Quality	Function: Manager Regulatory Affairs
Signature:	Signature:
Date of Approval: 26 Oct 2023	Date of Approval: 20-01-2023

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 26 Oct 2023	Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: 28-Sep-2022	Effective (Date or Lot Number): 26 Oct 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-OVERENSSTEMMELSE/ERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄT/ERKLÄRUNG	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 készletkiszorulás-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybos pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	EPH на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinствени регистрациски број) 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 unikalasis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

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

EN	Notified Body (Name and Identification Number)	Conformity Assessment Procedure
BG	Нотифициран орган (име и идентификационен номер)	Процедура за оценка на съответствието
CS	Oznámený subjekt (název a identifikační číslo)	Postup posuzování shody
DA	Bemyndiget organ (navn og identifikationsnummer)	Overensstemmelsesvurderingsprocedure
DE	Benannte Stelle (Name und Identifikationsnummer)	Konformitätsbewertungsverfahren
EL	Κοινοποιημένος Οργανισμός (Όνομα και Αριθμός ταυτοποίησης)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Organismo Notificado (nombre y número de identificación)	Procedimiento de evaluación de la conformidad
ET	Teavitatud asutus (nimi ja identifitseerimisnumber)	Vastavushindamismenetlus
FR	Organisme notifié (nom et numéro d'identification)	Procédure d'évaluation de la conformité
HR	Prijavljeno tijelo (naziv i identifikacijski broj)	Postupak ocjenjivanja sukladnosti
HU	Bejelentett szervezet (név és azonosító szám)	Megfelelőségértékelési eljárás
IT	Organismo notificato (nome e numero di identificazione)	Procedura di valutazione della conformità
LV	Pilnvarotā iestāde (nosaukums un identifikācijas numurs)	Atbilstības novērtēšanas procedūra
LT	Notifikuotoji įstaiga (pavadinimas ir identifikacinis numeris)	Atitikties vertinimo procedūra
NO	Meldt organ (navn og identifikasjonsnummer)	Framgangsmåte for samsvarsvurdering
PL	Jednostka notyfikowana (nazwa i numer identyfikacyjny)	Procedura oceny zgodności
PT	Organismo Notificado (Nome e Número de Identificação)	Procedimento de avaliação da conformidade
RO	Organism notificat (nume și număr de identificare)	Procedură de evaluare a conformității
SK	Notifikovaný orgán (Názov a identifikačné číslo)	Postup posudzovania zhody
SV	Anmält organ (namn och identifikationsnummer)	Förfarande för bedömning av överensstämmelse
TR	Onaylanmış Kuruluş (İsim ve Tanım Numarası)	Uygunluk Değerlendirme Prosedürü

EN	Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples
BG	Система за управление на качеството Приложение IX, глави I и III, включително оценка на техническата документация на съответните изделия въз основа на представителни проби
CS	Systém řízení kvality Příloha IX Kapitoly I a III, včetně posouzení technické dokumentace dotčených prostředků na základě reprezentativních vzorků
DA	Kvalitetsstyringssystem Bilag IX kapitel I og III, Herunder en vurdering af den tekniske dokumentation for relevant udstyr på baggrund af repræsentative prøver
DE	Qualitätsmanagementsystem Anhang IX Kapitel I und III, einschließlich einer Bewertung der Technischen Dokumentation für betroffene Produkte auf der Grundlage repräsentativer Stichproben
EL	Σύστημα Διαχείρισης Ποιότητας Παράρτημα IX Κεφάλαια I και III, συμπεριλαμβάνεται αξιολόγηση του τεχνικού φακέλου για προϊόντα που εξετάζονται με βάση αντιπροσωπευτικά δείγματα
ES	Sistema de Gestión de Calidad Anexo IX, capítulos I y III, se incluye una evaluación de la documentación técnica para los productos afectados sobre la base de muestras representativas
ET	Kvaliteedijuhtimissüsteem IX lisa I ja III peatükk Sealhulgas asjaomaste seadmete tehnilise dokumentatsiooni hindamist esindavate valimite põhjal
FR	Système de gestion de la qualité Annexe IX Chapitres I et III, Inclut une évaluation de la documentation technique pour les dispositifs concernés, sur la base d'échantillons représentatifs
HR	Sustav upravljanja kvalitetom Prilog IX., Poglavlja I. i III., uključujući ocjenjivanje tehničke dokumentacije za predmetne proizvode na temelju reprezentativnih uzoraka
HU	Minőségirányítási rendszer IX. melléklet, I. és III. fejezet, ideértve az érintett eszközök műszaki dokumentációjának reprezentatív minták alapján való értékelését
IT	Sistema di gestione della qualità Allegato IX Capitoli I e III, compresa una valutazione della documentazione tecnica per i dispositivi interessati sulla base di campioni rappresentativi
LV	Kvalitātes vadības sistēma IX pielikuma I un III nodaļa, tostarp attiecīgo ierīču tehniskās dokumentācijas novērtējums, pamatojoties uz reprezentatīviem paraugiem
LT	Kokybės valdymo sistema IX priedo I ir III skyriai, įskaitant atitinkamų priemonių techninės dokumentacijos vertinimą remiantis tipiniais pavyzdžiais
NO	Kvalitetsstyringssystem Vedlegg IX kapittel I og III, inkludert en vurdering av den tekniske dokumentasjonen for aktuelt utstyr på grunnlag av representative prøver
PL	System Zarządzania Jakością Załącznik IX, Rozdziały I oraz III, w tym ocena dokumentacji technicznej danych wyrobów na podstawie reprezentatywnych próbek
PT	Sistema de gestão da qualidade Anexo IX Capítulos I e III, Incluindo uma avaliação da documentação técnica para os dispositivos em questão com base em amostras representativas
RO	Sistemul de management al calității Anexa IX, Capitolele I și III inclusiv o evaluare a documentației tehnice pentru dispozitivele în cauză pe baza unor probe reprezentative.
SK	Systém riadenia kvality Príloha IX Kapitoly I a III, vrátane posúdenia technickej dokumentácie príslušných pomôcok na základe reprezentatívnych vzoriek
SV	Kvalitetsledningssystem Bilaga IX Kapitel I och III, Inklusive en bedömning av den tekniska dokumentationen för berörda produkter som grundar sig på representativa urval
TR	Kalite Yönetim Sistemi Ek IX Bölüm I ve III Temsili numuneler bazında ilgili cihazlar için teknik dokümantasyonun değerlendirilmesi dahil

EN	EU Certificate No.	Common Specifications (CS)	Full Name
BG	ЕС Сертификат №	Общи спецификации (OC)	Пълно наименование
CS	Číslo certifikátu EU	Společné specifikace	Celý název
DA	EU-certifikatnummer	Fælles specifikationer	Fulde navn
DE	Nr. des EU-Zertifikats	Gemeinsame Spezifikationen (GS)	Vollständiger Name
EL	Αριθμός πιστοποιητικού ΕΕ	Κοινές προδιαγραφές (ΚΠ)	Πλήρης ονομασία
ES	Número certificado UE	Especificaciones comunes	Nombre completo
ET	EL-i sertifikaadi nr	Ühtsed kirjeldused	Täisnimi
FR	N° certificat UE	Spécifications communes	Nom complet
HR	EU potvrda br.	Zajedničke specifikacije („CS“)	Puni naziv
HU	EU-tanúsítvány száma	Egységes előírások	Teljes név
IT	N° del certificato UE	Specifiche comuni (SC)	Nome completo
LV	ES sertifikāta Nr.	Kopīgās specifikācijas	Pilns nosaukums
LT	ES sertifikatas Nr.	Bendrosios specifikacijos	Vardas ir pavardė
NO	EU-sertifikatnr.	Felles spesifikasjoner	Fullt navn
PL	Nr Certyfikatu UE	Wspólne specyfikacje	Imię i nazwisko
PT	Certificado UE N°	Especificações comuns	Nome completo
RO	Nr. certificat UE:	Specificații comune (CS)	Numele complet
SK	Certifikát EÚ č.	Spoločné špecifikácie	Celý názov
SV	Nummer på EU-intyg	Gemensamma specifikationer	Fullständigt namn
TR	AB Sertifika Numarası	Genel Spesifikasyonlar (GS)	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 képviselőtében 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	Ustedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnăt pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	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	Ustedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställtigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	We, the undersigned, hereby declare that the <i>in vitro</i> diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>In Vitro</i> Diagnostic Medical Devices. 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) <i>in vitro</i> 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 <i>in vitro</i> . Toto prohlášení je v souladu s Přílohou IV nařízení IVD a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det <i>in vitro</i> -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 <i>in vitro</i> -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 υπογράφωντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5 ^{ης} Απριλίου 2017 σχετικά με τα <i>in vitro</i> 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 <i>in vitro</i> descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico <i>in vitro</i> . 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 <i>in vitro</i> diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (<i>in vitro</i> diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. 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 <i>in vitro</i> indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic <i>in vitro</i> . 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 <i>in vitro</i> dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o <i>in vitro</i> dijagnostičkim medicinskim proizvodima. 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 <i>in vitro</i> orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács <i>in vitro</i> 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) <i>in vitro</i> sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici <i>in vitro</i> . 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) <i>in vitro</i> diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par <i>in vitro</i> diagnostikas medicīniskām ierīcēm. 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) <i>in vitro</i> diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl <i>in vitro</i> diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til <i>in vitro</i> -diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til <i>in vitro</i> -diagnostikk. 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 <i>in vitro</i> spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki <i>in vitro</i> . 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 <i>in vitro</i> descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico <i>in vitro</i> . Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnatii, declaram ca dispozitivul (dispozitivele) medical(e) pentru diagnostic <i>in vitro</i> descrise mai sus sunt conforme cu dispozitiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European si al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul <i>in vitro</i> . Prezenta declaratie este emisa in conformitate cu anexa IV la Regulamentul IVD si este emisa sub responsabilitatea exclusiva a producatorului.
SK	My, dolupodpisani, týmto vyhlasujeme, že diagnostický(-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 zdravotníckych pomôckach <i>in vitro</i> . 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 <i>in vitro</i> -diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för <i>in vitro</i> -diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen <i>in vitro</i> diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli <i>In Vitro</i> Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.



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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 010051 0103 Rev. 13

Manufacturer: **Abbott GmbH**
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Product Category(ies): Products for determination of infection markers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1_010051_0103_Rev.13

Report no.: 713237273-04_SCN

Valid from: 2022-05-10
Valid until: 2025-05-26

Date, 2022-05-10

Christoph Dicks
Head of Certification/Notified Body



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No. V1 010051 0103 Rev. 13

Model(s): Products for the determination of
infection markers for HIV, Hepatitis B,
Hepatitis C, HTLV, toxoplasmosis

Facility(ies): Abbott GmbH
Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

The products detailed below are covered under the scope of this certificate:

Annex II List A Products

Product Name	REF N°
ABBOTT PRISM HIV O Plus Assay Kit	3D34-48
ABBOTT PRISM HBsAg Assay Kit	3A47-48
ABBOTT PRISM HCV Assay Kit	6A52-48
ABBOTT PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
ABBOTT PRISM Positive Run Control Kit	5E22-11
ABBOTT PRISM Run Control Kit	5E22-10
ABBOTT PRISM HBcore Assay Kit	1A77-48
ABBOTT PRISM HBsAg Confirmatory Assay Kit	6D16-48
ABBOTT PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
ABBOTT PRISM Run Control Kit	2K24-10
ABBOTT PRISM Positive Run Control Kit	2K24-11
ARCHITECT Anti-HCV Reagent Kit	6C37-22
ARCHITECT Anti-HCV Reagent Kit	6C37-27
ARCHITECT Anti-HCV Reagent Kit	6C37-32
ARCHITECT Anti-HCV Reagent Kit	6C37-37
ARCHITECT Anti-HCV Calibrator	6C37-01
ARCHITECT Anti-HCV Controls	6C37-10
ARCHITECT Anti-HCV Reagent Kit	6C37-28
ARCHITECT Anti-HCV Reagent Kit	6C37-33
ARCHITECT Anti-HCV Reagent Kit	6C37-38
ARCHITECT Anti-HCV Calibrator	6C37-02
ARCHITECT Anti-HCV Controls	6C37-15
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-22
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-27
ARCHITECT Anti-HBc IgM Calibrators	6C33-02
ARCHITECT Anti-HBc IgM Controls	6C33-11
ARCHITECT Anti-HBe Reagent Kit	6C34-20
ARCHITECT Anti-HBe Reagent Kit	6C34-25
ARCHITECT Anti-HBe Reagent Kit	6C34-35
ARCHITECT Anti-HBe Calibrator	6C34-01
ARCHITECT Anti-HBe Controls	6C34-10

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Annex II List A Products

Product Name	REF N°
ARCHITECT HBeAg Reagent Kit	6C32-20
ARCHITECT HBeAg Reagent Kit	6C32-25
ARCHITECT HBeAg Reagent Kit	6C32-27
ARCHITECT HBeAg Reagent Kit	6C32-37
ARCHITECT HBeAg Calibrators	6C32-01
ARCHITECT HBeAg Quantitative Calibrators	7P24-01
ARCHITECT HBeAg Controls	6C32-10
ARCHITECT HBeAg Quantitative Controls	7P24-10
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
ARCHITECT rHTLV I/II Reagent Kit	6L61-25
ARCHITECT rHTLV I/II Reagent Kit	6L61-30
ARCHITECT rHTLV I/II Reagent Kit	6L61-35
ARCHITECT rHTLV I/II Calibrator	6L61-01
ARCHITECT rHTLV I/II Controls	6L61-10
ARCHITECT Anti-HBc II Reagent Kit	8L44-25
ARCHITECT Anti-HBc II Reagent Kit	8L44-30
ARCHITECT Anti-HBc II Reagent Kit	8L44-35
ARCHITECT Anti-HBc II Calibrator	8L44-01
ARCHITECT Anti-HBc II Controls	8L44-10
ARCHITECT HCV Ag Controls	6L47-11
ARCHITECT HCV Ag Controls	6L47-19
ARCHITECT HCV Ag Calibrators	6L47-02
ARCHITECT HCV Ag Calibrators	6L47-09
ARCHITECT HCV Ag Reagent Kit	6L47-29
ARCHITECT HCV Ag Reagent Kit	6L47-74



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Annex II List A Products

Product Name	REF N°
Alinity i Anti-HBe Reagent Kit	07P6322
Alinity i Anti-HBe Reagent Kit	07P6332
Alinity i Anti-HBe Calibrator	07P6301
Alinity i Anti-HBe Controls	07P6310
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0722
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0732
Alinity i HIV Ag/Ab Combo Calibrator	08P0701
Alinity i HIV Ag/Ab Combo Controls	08P0710
Alinity i Anti-HCV Reagent Kit	08P0622
Alinity i Anti-HCV Reagent Kit	08P0632
Alinity i Anti-HCV Calibrator	08P0601
Alinity i Anti-HCV Controls	08P0610
Alinity i Anti-HCV Reagent Kit	08P0623
Alinity i Anti-HCV Reagent Kit	08P0633
Alinity i Anti-HCV Calibrator	08P0602
Alinity i Anti-HCV Controls	08P0611
Alinity i Anti-HBc IgM Reagent Kit	07P8622
Alinity i Anti-HBc IgM Calibrators	07P8601
Alinity i Anti-HBc IgM Controls	07P8610
Alinity i Anti-HBc II Reagent Kit	07P8722
Alinity i Anti-HBc II Reagent Kit	07P8732
Alinity i Anti-HBc II Calibrator	07P8701
Alinity i Anti-HBc II Controls	07P8710
Alinity i HCV Ag Reagent Kit	09P2322
Alinity i HCV Ag Controls	09P2310
Alinity i HCV Ag Calibrators	09P2301



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Annex II List A Products

Product Name

REF N°

Alinity i rHTLV-I/II Reagent Kit	07P6122
Alinity i rHTLV-I/II Reagent Kit	07P6132
Alinity i rHTLV-I/II Calibrator	07P6101
Alinity i rHTLV-I/II Controls	07P6110
Alinity i HBeAg Reagent Kit	07P6422
Alinity i HBeAg Reagent Kit	07P6432
Alinity i HBeAg Calibrators	07P6401
Alinity i HBeAg Controls	07P6410
Alinity i HBeAg Quantitative Calibrators	09P1001
Alinity i HBeAg Quantitative Controls	09P1010
Alinity s Anti-HBc Reagent Kit	06P0655
Alinity s Anti-HBc Calibrator Kit	06P0602
Alinity s Anti-HBc Assay Control Kit	06P0610
Alinity s Anti-HBc Release Control Kit	06P0612
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0155
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0102
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0110
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0112
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0160
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0103
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0120
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0124



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Annex II List A Products

Product Name	REF N°
Alinity s Anti-HCV Reagent Kit	06P0455
Alinity s Anti-HCV Calibrator Kit	06P0402
Alinity s Anti-HCV Assay Control Kit	06P0410
Alinity s Anti-HCV Release Control Kit	06P0412
Alinity s Anti-HCV Reagent Kit	06P0477
Alinity s Anti-HCV Calibrator Kit	06P0409
Alinity s Anti-HCV Assay Control Kit	06P0419
Alinity s Anti-HCV Release Control Kit	06P0418
Alinity s Anti-HCV Reagent Kit	06P0460
Alinity s Anti-HCV Calibrator Kit	06P0403
Alinity s Anti-HCV Assay Control Kit	06P0420
Alinity s Anti-HCV Release Control Kit	06P0424
Alinity s Anti-HCV II Reagent Kit	04W5655
Alinity s Anti-HCV II Reagent Kit	04W5656
Alinity s Anti-HCV II Calibrator Kit	04W5602
Alinity s Anti-HCV II Assay Control Kit	04W5610
Alinity s Anti-HCV II Release Control Kit	04W5612
Alinity s HTLV I/II Reagent Kit	06P0755
Alinity s HTLV I/II Calibrator Kit	06P0702
Alinity s HTLV I/II Assay Control Kit	06P0710
Alinity s HTLV I/II Release Control Kit	06P0712
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0177
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0109
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0119
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0118





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No. V1 010051 0103 Rev. 13

Annex II List A Products for ARCHITECT Plattform

Product Name	REF N°
Anti-HCV Reagent Kit	6C37-74
Anti-HCV Reagent Kit	6C37-77
Anti-HCV Reagent Kit	6C37-78
Anti-HCV Calibrator	6C37-09
Anti-HCV Controls	6C37-19
Anti-HBc IgM Reagent Kit	6C33-74
Anti-HBc IgM Reagent Kit	6C33-75
Anti-HBc IgM Calibrators	6C33-09
Anti-HBc IgM Controls	6C33-19
Anti-HBe Reagent Kit	6C34-74
Anti-HBe Reagent Kit	6C34-77
Anti-HBe Calibrator	6C34-09
Anti-HBe Controls	6C34-19
HBeAg Reagent Kit	6C32-74
HBeAg Reagent Kit	6C32-77
HBeAg Calibrators	6C32-09
HBeAg Quantitative Calibrators	7P24-09
HBeAg Controls	6C32-19
HBeAg Quantitative Controls	7P24-19
HIV Ag/Ab Combo Reagent Kit	4J27-74
HIV Ag/Ab Combo Reagent Kit	4J27-77
HIV Ag/Ab Combo Reagent Kit	4J27-78
HIV Ag/Ab Combo Reagent Kit	4J27-84
HIV Ag/Ab Combo Reagent Kit	4J27-87
HIV Ag/Ab Combo Reagent Kit	4J27-89
HIV Ag/Ab Combo Calibrator	4J27-09
HIV Ag/Ab Combo Controls	4J27-19
HIV Ag/Ab Combo Controls	4J27-17
Anti-HBc II Reagent Kit	8L44-74
Anti-HBc II Reagent Kit	8L44-77
Anti-HBc II Reagent Kit	8L44-78
Anti-HBc II Calibrator	8L44-09
Anti-HBc II Controls	8L44-19



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ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 010051 0103 Rev. 13

Annex II List A Products for Alinity i Plattform
Product Name

REF N°

Anti-HBe Reagent Kit	07P6374
Anti-HBe Reagent Kit	07P6377
Anti-HBe Calibrator	07P6309
Anti-HBe Controls	07P6319
HIV Ag/Ab Combo Reagent Kit	08P0774
HIV Ag/Ab Combo Reagent Kit	08P0777
HIV Ag/Ab Combo Reagent Kit	08P0784
HIV Ag/Ab Combo Reagent Kit	08P0787
HIV Ag/Ab Combo Calibrator	08P0709
HIV Ag/Ab Combo Controls	08P0719
HIV Ag/Ab Combo Controls	08P0717
Anti-HCV Reagent Kit	08P0674
Anti-HCV Reagent Kit	08P0677
Anti-HCV Calibrator	08P0609
Anti-HCV Controls	08P0619
Anti-HBc II Reagent Kit	07P8774
Anti-HBc II Reagent Kit	07P8777
Anti-HBc II Calibrator	07P8709
Anti-HBc II Controls	07P8719
Anti-HBc IgM Reagent Kit	07P8674
Anti-HBc IgM Calibrators	07P8609
Anti-HBc IgM Controls	07P8619
HBeAg Reagent Kit	07P6474
HBeAg Reagent Kit	07P6477
HBeAg Calibrators	07P6409
HBeAg Controls	07P6419
HBeAg Quantitative Calibrators	09P1009
HBeAg Quantitative Controls	09P1019



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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 010051 0103 Rev. 13

Annex II List B Products

Product Name	REF N°
ARCHITECT Toxo IgG Reagent Kit	6C19-25
ARCHITECT Toxo IgG Reagent Kit	6C19-35
ARCHITECT Toxo IgG Calibrators	6C19-01
ARCHITECT Toxo IgG Controls	6C19-10
ARCHITECT Toxo IgG Avidity Reagent Kit	6L37-25
ARCHITECT Toxo IgG Avidity Calibrator & Controls	6L37-11
ARCHITECT Toxo IgM Reagent Kit	6C20-25
ARCHITECT Toxo IgM Reagent Kit	6C20-35
ARCHITECT Toxo IgM Calibrator	6C20-01
ARCHITECT Toxo IgM Controls	6C20-10
Alinity i Toxo IgG Reagent Kit	07P4522
Alinity i Toxo IgG Reagent Kit	07P4532
Alinity i Toxo IgG Calibrators	07P4501
Alinity i Toxo IgG Controls	07P4510
Alinity i Toxo IgM Reagent Kit	07P4722
Alinity i Toxo IgM Reagent Kit	07P4732
Alinity i Toxo IgM Calibrator	07P4701
Alinity i Toxo IgM Controls	07P4710
Alinity i Toxo IgG Avidity Reagent Kit	07P4622
Alinity i Toxo IgG Avidity Controls	07P4610



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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 010051 0103 Rev. 13

Annex II List B Products for ARCHITECT Plattform

Product Name	REF N°
Toxo IgG Calibrators	6C19-09
Toxo IgG Controls	6C19-19
Toxo IgG Reagent Kit	6C19-74
Toxo IgG Reagent Kit	6C19-77
Toxo IgM Calibrators	6C20-09
Toxo IgM Controls	6C20-19
Toxo IgM Reagent Kit	6C20-74
Toxo IgM Reagent Kit	6C20-77
Toxo IgG Avidity Reagent Kit	6L37-74

Annex II List B Products for Alinity i Plattform

Product Name	REF N°
Toxo IgG Calibrators	07P4509
Toxo IgG Controls	07P4519
Toxo IgG Reagent Kit	07P4574
Toxo IgG Reagent Kit	07P4577
Toxo IgM Calibrators	07P4709
Toxo IgM Controls	07P4719
Toxo IgM Reagent Kit	07P4774
Toxo IgM Reagent Kit	07P4777
Toxo IgG Avidity Reagent Kit	07P4674



Product Service

Confirmation Statement on validity of EC Certificate (IVDD)
pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices
No. VCQ 010051 0149 Rev. 00

Manufacturer: **Abbott GmbH**
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

This Confirmation Statement **V1 010051 0103 Rev. 13**
is only valid in combination
with the following
EC Certificate (IVDD):

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2022 or later.

The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic
medical devices for placing devices on the market and putting into service apply. For details and
confirmation statement validity see: [www.tuvsud.com/ps-cert?q=cert:VCQ 010051 0149 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:VCQ_010051_0149_Rev.00)

Report No.: 713283413-03

Valid until: 2025-05-26

Issue Date: 2023-07-11

Marta Carnielli
Head of Notified Body IVD



Product Service

Confirmation Statement on validity of EC Certificate (IVDD)
pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices
No. VCQ 010051 0149 Rev. 00

Product Category(ies): Products for the determination of infection markers for HIV, Hepatitis B, Hepatitis C, HTLV, toxoplasmosis

Description of Change:

Removal of Products according to Annex II List A Devices:

Product Name	REF N°
Abbott PRISM HBcore Assay Kit	1A77-48
Abbott PRISM Run Control Kit	2K24-10
Abbott PRISM Run Control Kit	5E22-10
Abbott PRISM HBsAg Assay Kit	3A47-48
Abbott PRISM HIV O Plus Assay Kit	3D34-48
Abbott PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
Abbott PRISM HCV Assay Kit	6A52-48
Abbott PRISM HBsAg Confirmatory Assay Kit	6D16-48
Abbott PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
Abbott PRISM Positive Run Control Kit	2K24-11
Abbott PRISM Positive Run Control Kit	5E22-11





Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that



Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany

has established and applies
a Quality Management System for

**Design and Development, Manufacture and Warehousing of
In-vitro Diagnostic Reagents for Clinical Chemistry,
Immunochemistry, Hematology and Infectious Immunology.
The provision of Warehousing and Distribution services of
In-Vitro Diagnostic Medical Devices and Medical Devices
*including the sites and scope of application see enclosure.***

An audit was performed, Order No. **707151799**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2022-09-14** until **2024-09-30**.

Certificate Registration No.: **12 100 64551 TMS**.

Head of Certification Body
Munich, 2022-09-15





Management Service

Enclosure of Certificate Registration No.: 12 100 64551 TMS

Sites	Scope of application
Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany	Design and Development, Manufacture and Warehousing of In-vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology and Infectious Immunology
Abbott Diagnostics GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany	The provision of Warehousing and Distribution services of In-Vitro Diagnostic Medical Devices and Medical Devices

Head of Certification Body
Munich, 2022-09-15





America

CERTIFICATE

No. QS6 010051 0140 Rev. 02

Certificate Holder:

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Manufacture and Distribution of In-Vitro Diagnostics Reagents used in the Diagnosis, Management and Detection of Blood Analytes, Immune Status, Complement Components, Cancer, Thyroid Markers, Fertility Testing, Endocrine Disorders, Bone and Mineral Metabolism, Hormones, Vitamins, Therapeutic Drug Monitoring, Rheumatoid - Inflammatory Diseases, Cardiac Markers, Immunological Typing Bacterial Infectious Diseases, Viral Infectious Diseases, and Parasitic Infectious Diseases

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6 010051 0140 Rev. 02

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

REPs Facility ID:

F006151

Report No.:

713296312

Effective Date:

2023-06-20

Expiry Date:

2024-09-30

Page 1 of 2

Date of Issue: 2023-06-26

(Renee Walker)
Director, US Certification Body, MHS

CERTIFICATE

No. QS6 010051 0140 Rev. 02

Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.155 (2020)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Abbott GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

Facility Scopes:

Design and Development, Manufacture and Distribution of In-Vitro Diagnostics Reagents used in the Diagnosis, Management and Detection of Blood Analytes, Immune Status, Complement Components, Cancer, Thyroid Markers, Fertility Testing, Endocrine Disorders, Bone and Mineral Metabolism, Hormones, Vitamins, Therapeutic Drug Monitoring, Rheumatoid - Inflammatory Diseases, Cardiac Markers, Immunological Typing Bacterial Infectious Diseases, Viral Infectious Diseases, and Parasitic Infectious Diseases
REPs Facility ID: F006151

Page 2 of 2

Date of Issue: 2023-06-26



(Renee Walker)
Director, US Certification Body, MHS



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 010051 0137 Rev. 03

Manufacturer:

Abbott GmbH

Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

SRN Manufacturer - DE-MF-000009455

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 010051 0137 Rev. 03

Report No.: 713296312-CN

Preceding Certificate No.: V12 010051 0137 Rev. 02

Valid from: 2023-07-03

Valid until: 2026-08-11

Date of Initial Issuance: 2021-08-12

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-07-03



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 010051 0137 Rev. 03

Classification:	Class B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
Classification:	Class B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	Class B
Device Group:	W0105 - INFECTIOUS DISEASES
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
Classification:	Class C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer
Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 010051 0137 Rev. 03

Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer
Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
Classification:	Class C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0501 - Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
The validity of this certificate depends on conditions and/or is limited to the following:	-none-



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BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 010051 0137 Rev. 03

Revision History:

Rev.	Dated	Report	Description
00	2021-08-12	713198378	-
01	2022-03-22	713234659-02	-
02	2022-10-13	713234659-04	-
03	2023-07-03	713296312-CN	Supplemented: Device(s)/group of device(s) added

Declaration of Conformity

Certificate Identification: 7K63
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K63-27 7K63-32 7K63-37	54417	ARCHITECT Free T ₃ Reagent Kit	Self-declared
7K63-02	38261	ARCHITECT Free T ₃ Calibrators	Self-declared
7K63-12	54418	ARCHITECT Free T ₃ Controls	Self-declared
Authorized European Representative (Name and Address)		N/A	
Storage of technical documentation (Name and Address)		Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland	
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: Siobhan Wright

Full Name: **Siobhan Wright**

Position: **Director Quality Assurance/
Site Quality Head**

Date of Approval: 01-MAY-2020

Date Issued: 01-MAY-2020

Supersedes: 24-April-2019

Signature: Lorraine Whitney

Full Name: **Lorraine Whitney**

Position: **Senior Manager
Regulatory Affairs**

Date of Approval: 01 MAY 2020

Place Issued: **Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford,
Ireland.**

Effective (Date or Lot Number): 01-MAY-2020

Declaration of Conformity

Certificate Identification:	7K65-22/-24/-27/-29/-32/-34/-35/-39, 7K65-02, 7K65-10
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

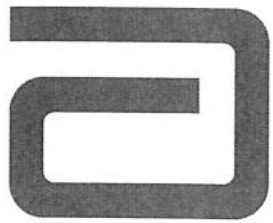
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K65-22 7K65-24 7K65-27 7K65-29 7K65-32 7K65-34 7K65-35 7K65-39	54413	ARCHITECT Free T4 Reagent Kit	Self-declared
7K65-02	38259	ARCHITECT Free T4 Calibrators	Self-declared
7K65-10	38258	ARCHITECT Free T4 Controls	Self-declared
Authorized European Representative (Name and Address)		N/A	
Storage of site technical documentation (Name and Address)		Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.	
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: *Siobhan Wright*
 Full Name: **Siobhan Wright**
 Position: **Director Quality Assurance/
Site Quality Head**
 Date of Approval: 29-APR-19
 Date Issued: 29-APR-19
 Supersedes: 26-July-2017

Signature: *p.p. SANDRA GALLAGHER S. Gallagher*
 Full Name: **Lorraine Whitney**
 Position: **Senior Manager Regulatory Affairs**
 Date of Approval: 25-APR-2019
 Place Issued: **Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford,
Ireland**
 Effective (Date or Lot Number): 29-APR-19



Memo

To Whom it may concern

I will be out of office Tues 23rd to Fri 26th April 19.

My signature during this time is delegated to Noel Haren and Sandra Gallagher.

Lorraine Whitney 19 APR 2019

Lorraine Whitney

Senior Manager Regulatory Affairs

Site Operations Ireland