ЕС декларация за съответствие

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Германия
SRN	DE-MF-000027747

Декларираме единствено на наша отговорност, че долупосочените продукти съответстват на всички приложими изисквания на Регламент (ЕС) 2017/746 за медицинските изделия за диагностика *in vitro*.

Информация за продукта		
Наименование	**Базов UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Класификация на риска (съгласно приложение VIII)

A ☐ B ☒ C ☐ D ☐

Процедури за оценяване на съответствието

☒ ПРИЛОЖЕНИЕ IX Цялостна система за управление на качеството (клас B, C, D)	Сертификат на ЕС №	D1060500064 in accordance with supplement D1060500065
	Нотифициран орган:	mdc medical device certification GmbH
	Идентификационен номер:	0483
☐ ПРИЛОЖЕНИЕ IX Проверка на техническата документация (клас D)	Сертификат на ЕС №	
	Нотифициран орган:	mdc medical device certification GmbH
	Идентификационен номер:	0483
☐ ПРОВЕРКА I & II + III (клас A, нестерилно)		
☐ Общи спецификации (ОС):		
☒ хармонизирани стандарти, национални стандарти, други нормативни документи: вж. приложението за списък на стандартите		

Срок на валидност на ЕС декларацията за съответствие	**09.01.2029**

От името на MIKROGEN GmbH, изпълнителен директор д-р Erwin Soutschek:

i.V.	Neuried	28.08.2025
подпис	издадено в	дата
Dr. Eva Felder	QMB	
име	длъжно	

Приложение със списък на стандартите

Документ № + версия	Заглавие
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

при необходимост добави допълнителни цифри

EU prohlášení o shodě

	MIKROGEN GmbH Anna-Sigmund-Straße 10 82061 Neuried Německo
SRN	DE-MF-000027747

Prohlašujeme na vlastní odpovědnost, že níže uvedené výrobky splňují všechny platné požadavky nařízení (EU) 2017/746 o diagnostických zdravotnických prostředcích *in vitro*.

Informace o výrobku		
Název	**Základní UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Klasifikace rizika (podle přílohy VIII)

A ☐ B ☒ C ☐ D ☐

Metoda posuzování shody

☒ PŘÍLOHA IX Kompletní systém kvality (třída B, C, D)	Č. certifikátu EU:	D1060500064 in accordance with supplement D1060500065
	Notifikovaná osoba:	mdc medical device certification GmbH
	Identifikační č.:	0483
☐ PŘÍLOHA IX Ověření technické dokumentace (třída D)	Č. certifikátu EU:	
	Notifikovaná osoba:	mdc medical device certification GmbH
	Identifikační č.:	0483
☐ PŘÍLOHA I, II a III (třída A, není sterilní)		
☐ Společné specifikace:		
☒ Harmonizované normy, národní normy, jiné normativní dokumenty: viz příloha seznam norem		

Doba platnosti prohlášení o shodě	**09.01.2029**

Za MIKROGEN GmbH jednatel dr. Erwin Soutschek:

i.V. _____ Neuried 28.08.2025

Podpis Místo Datum

Dr. Eva Felder QMB

Jmén Funkce

Příloha Seznam norem

Číslo dokumentu + číslo vydání	Titulek
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
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EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

v případě potřeby přidejte další řádky

EU-Konformitätserklärung

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Deutschland
SRN	DE-MF-000027747

Wir erklären in alleiniger Verantwortung, dass die unten aufgelisteten Produkte allen anwendbaren Anforderungen der Verordnung (EU) 2017/746 über *In-vitro*-Diagnostika entsprechen.

Produktinformationen		
Name	**Basis UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Risikoklassifizierung (nach Annex VIII)

A ☐ B ☒ C ☐ D ☐

Konformitätsbewertungsverfahren

☒ ANHANG IX Vollständiges Qualitätssystem (Klasse B, C, D)	EU-Zertifikat Nr.:	D1060500064 in accordance with supplement D1060500065
	Benannte Stelle:	mdc medical device certification GmbH
	Kennnummer:	0483
☐ ANHANG IX Prüfung der Technischen Dokumentation (Klasse D)	EU-Zertifikat Nr.:	
	Benannte Stelle:	mdc medical device certification GmbH
	Kennnummer:	0483
☐ ANHANG I & II + III (Klasse A, nicht steril)		
☐ Gemeinsame Spezifikationen (GS):		
☒ harmonisierte Normen, nationale Normen, andere normative Dokumente: siehe Anhang Liste Normen		

Gültigkeitsdauer der Konformitätserklärung	**09.01.2029**

Im Namen der MIKROGEN GmbH, Geschäftsführer Dr. Erwin Soutschek:

i.V. _____ Neuried 28.08.2025

Unterschrift | ausgestellt in | Datum

Dr. Eva Felder | QMB

Name | Funktion

DoC_04_DE

Anhang Liste Normen

Dokumenten-Nr. + Ausgabestand	Titel
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

bei Bedarf weitere Zeilen hinzufügen

MIKROGEN
DIAGNOSTIK

EU Declaration of Conformity

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Germany
SRN	DE-MF-000027747

We declare under our sole responsibility that the products listed below meet the provisions of the regulation (EU) 2017/746 on *in vitro* diagnostic medical devices which apply to it.

Product Information		
Name	**Basic UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Risk Classification (according Annex VIII)

A ☐ B ☒ C ☐ D ☐

Conformity Assessment Procedure

☒ ANNEX IX Full Quality System (Class B, C, D)	EU-Certificate #.:	D1060500064 in accordance with supplement D1060500065
	Notified Body	mdc medical device certification GmbH
	Notified Body Identification:	0483
☐ ANNEX IX Technical Documentation Examination (Class D)	EU-Certificate #.:	
	Notified Body	mdc medical device certification GmbH
	Notified Body Identification:	0483
☐ ANNEX I & II + III (Class A, non-sterile)		
☐ Common Specifications (CS):		
☒ Harmonised standards, national standards, other normative documents: see annex list of standards		

Period of validity of the declaration of conformity	**09.01.2029**

On behalf of MIKROGEN GmbH, Managing Director Dr. Erwin Soutschek:

i.V.	Neuried	28.08.2025
Signature	Issued in	Date
Dr. Eva Felder	QMB	
Name	Function	

DoC_04_EN

Annex List of Standards

Document no. + issue status	Title
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Add more lines if needed

Declaración de conformidad de la UE

	MIKROGEN GmbH Anna-Sigmund-Straße 10 82061 Neuried Alemania
SRN	DE-MF-000027747

Declaramos bajo nuestra exclusiva responsabilidad que los productos abajo enumerados cumplen todos los requisitos aplicables del Reglamento (UE) 2017/746 sobre productos sanitarios para diagnóstico *in vitro*.

Información del producto		
Nombre	**UDI-DI básico**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Clasificación de riesgos (según el anexo VIII)

A ☐ B ☒ C ☐ D ☐

Procedimiento de evaluación de la conformidad

☒ ANEXO IX Sistema de calidad completo (clase B, C, D)	N.° de certificado UE:	D1060500064 in accordance with supplement D1060500065
	Organismo notificado:	mdc medical device certification GmbH
	Número de identificación:	0483
☐ ANEXO IX Comprobación de la documentación técnica (clase D)	N.° de certificado UE:	
	Organismo notificado:	mdc medical device certification GmbH
	Número de identificación:	0483
☐ ANEXOS I y II + III (clase A, no estéril)		
☐ Especificaciones comunes (EC):		
☒ Normas armonizadas, normas nacionales, otros documentos normativos: véase el apéndice lista de normas		

Período de validez de la declaración de conformidad	**09.01.2029**

En representación de MIKROGEN GmbH, Director Dr. Erwin Soutschek:

i.V. — Firma

Neuried — expedido en

28.08.2025 — Fecha

Dr. Eva Felder — Nom

QMB — Función

DoC_04_ES

Anexo Lista de normas

Nº de documento + estado de emisión	Título
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Añada más líneas si es necesario

Déclaration de conformité UE

	MIKROGEN GmbH Anna-Sigmund-Straße 10 82061 Neuried Allemagne
SRN	DE-MF-000027747

Nous déclarons sous notre seule responsabilité que les produits listés ci-dessous sont conformes à toutes les exigences applicables du règlement (UE) 2017/746 relatif aux dispositifs médicaux de diagnostic *in vitro*.

Informations sur le produit		
Nom	**Basis UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Classification des risques (par annexe VIII)

A ☐ B ☒ C ☐ D ☐

Procédures d'évaluation de la conformité

☒ ANNEXE IX Système de qualité complet (Classe B, C, D)	No de certificat UE :	D1060500064 in accordance with supplement D1060500065
	Organisme désigné :	mdc medical device certification GmbH
	Numéro d'identification :	0483
☐ ANNEXE IX Évaluation de la documentation technique (classe D)	No de certificat UE :	
	Organisme désigné :	mdc medical device certification GmbH
	Numéro d'identification :	0483
☐ ANNEXE I & II + III (Classe A, non stérile)		
☐ Spécifications communes (SC):		
☒ normes harmonisées, normes nationales, autres documents normatifs : voir annexe Liste des normes		

Durée de validité de la déclaration de conformité	**09.01.2029**

Au nom de MIKROGEN GmbH, gérant Dr Erwin Soutschek :

i.V. _____ Neuried 28.08.2025

Signature — délivré à — Date

Dr. Eva Felder — QMB

Nom — Fonction

DoC_04_FR

Annexe Liste des normes

N° de document + état des dépenses	Titre
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
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EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

ajouter des lignes supplémentaires si nécessaire

MIKROGEN DIAGNOSTIK

EU izjava o sukladnosti

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Njemačka
SRN	DE-MF-000027747

Uz isključivu odgovornost izjavljujemo da dolje navedeni proizvodi odgovaraju svim primjenjivim zahtjevima Uredbe (EU) 2017/746 o *in-vitro* dijagnostici.

Informacije o proizvodu		
Naziv	**Osnovni UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Klasifikacija rizika (prema Dodatku VIII)

A ☐ B ☒ C ☐ D ☐

Postupak ocjene sukladnosti

☒ Dodatak IX Kompletni sustav kvalitete (klasa B, C, D)	Br. EU certifikata:	D1060500064 in accordance with supplement D1060500065
	Prijavljeno tijelo:	mdc medical device certification GmbH
	Identifikacijski broj:	0483
☐ Dodatak IX Provjera tehničke dokumentacije (klasa D)	Br. EU certifikata:	
	Prijavljeno tijelo:	mdc medical device certification GmbH
	Identifikacijski broj:	0483
☐ DODATAK I te II + III (klasa A, nije sterilno)		
☐ Zajedničke specifikacije (GS):		
☒ harmonizirane norme, nacionalne norme, drugi normativni dokumenti: vidjeti dodatak s popisom normi		

Trajanje važenja izjave o sukladnosti	**09.01.2029**

U ime tvrtke MIKROGEN GmbH, direktor dr. Erwin Soutschek:

i.V.	Neuried	28.08.2025
Potpis	Mjesto	Datum
Dr. Eva Felder	QMB	
Ime	Funkcija	

Dodatak: Popis normi

Br. dokumenta + revizija	Naslov
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
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EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
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EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

po potrebi dodati još redaka

EU megfelelőségi nyilatkozat

	MIKROGEN GmbH Floriansbogen 2-4 82061 Neuried Németország
SRN	DE-MF-000027747

Kizárólagos felelősségünk tudatában kijelentjük, hogy az alább felsorolt termékek megfelelnek az *in-vitro* diagnosztikára vonatkozó (EU) 2017/746 rendelkezés minden alkalmazható követelményének.

Termékinformáció		
Név	**Alap UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Kockázatminősítés (a melléklet szerint VIII)

A ☐ B ☒ C ☐ D ☐

Megfelelőség-értékelési eljárás

☒ IX. FÜGGELÉK Teljes minőségrendszer (B, C, D osztály)	EU tanúsítvány száma:	D1060500064 in accordance with supplement D1060500065
	Bejelentett szervezet:	mdc medical device certification GmbH
	Azonosító szám:	0483
☐ IX. FÜGGELÉK Műszaki dokumentáció vizsgálata (D osztály)	EU tanúsítvány száma:	
	Bejelentett szervezet:	mdc medical device certification GmbH
	Azonosító szám:	0483
☐I. & II. + III. FÜGGELÉK (A osztály, nem steril)		
☐ Közös specifikációk (GS):		
☒ Harmonizált szabványok, nemzeti szabványok, egyéb normatív dokumentumok: lásd a függelékben a szabványok listáját		

A megfelelőségi nyilatkozat érvényességi ideje	**09.01.2029**

A MIKROGEN GmbH nevében Dr. Erwin Soutschek vezérigazgató:

i.V. — Neuried — 28.08.2025

Aláírás | kiállítás | Dátum

~~Dr. Eva Felder~~ — ~~QMB~~

Név | Beosztás

DoC_04_HUN

Mellékletjegyzék Szabványok

Dokumentumszám + kiadás állapota	Cím
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Szükség esetén adjon hozzá további sorokat

Dichiarazione di conformità UE

	MIKROGEN GmbH Anna-Sigmund-Straße 10 82061 Neuried Germania
numero di registrazione unico SRN	DE-MF-000027747

Dichiariamo sotto la nostra esclusiva responsabilità che i prodotti sotto elencati soddisfano tutti i requisiti applicabili del regolamento (UE) 2017/746 riguardante la diagnostica *in-vitro*.

Informazioni sul prodotto		
Nome	**UDI-DI di base**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Classificazione del rischio (secondo l'allegato VIII)

A ☐ B ☒ C ☐ D ☐

Procedura di valutazione della conformità

☒ ALLEGATO IX Sistema completo per la qualità (Classe B, C, D)	Certificato UE n.:	D1060500064 in accordance with supplement D1060500065
	Organismo notificato:	mdc medical device certification GmbH
	Numero di identificazione:	0483
☐ ALLEGATO IX Controllo della documentazione tecnica (classe D)	Certificato UE n.:	
	Organismo notificato:	mdc medical device certification GmbH
	Numero di identificazione:	0483
☐ ALLEGATO I & II + III (Classe A, non sterile)		
☐ Specifiche comuni (SC):		
☒ Norme armonizzate, norme nazionali, altri documenti normativi: vedere l'elenco degli standard in appendice		

Periodo di validità della dichiarazione di conformità	09.01.2029

A nome di MIKROGEN GmbH, Amministratore Dr. Erwin Soutschek:

i.V.

Firma	Rilasciato a	Data
	Neuried	28.08.2025
Dr. Eva Felder	QMB	
Nom	Funzion	

Elenco degli allegati Norme

Numero del documento + stato di emissione	Titolo
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Aggiungere altre righe se necessario

MIKROGEN
DIAGNOSTIK

Declaração de conformidade UE

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Alemanha
SRN	DE-MF-000027747

Declaramos sob nossa inteira responsabilidade que os produtos abaixo listados cumprem todas as exigências aplicáveis do regulamento (UE) 2017/746 relativo a diagnósticos *in-vitro*.

Informações sobre o produto		
Nome	**UDI-DI básico**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Classificação do risco (de acordo com o anexo VIII)

A ☐ B ☒ C ☐ D ☐

Procedimento de avaliação da conformidade

☒ ANEXO IX Sistema de qualidade completo (categoria B, C, D)	Certificado UE n.º:	D1060500064 in accordance with supplement D1060500065
	Organismo notificado:	mdc medical device certification GmbH
	Número de identificação	0483
☐ ANEXO IX Verificação da documentação técnica (categoria D)	Certificado UE n.º:	
	Organismo notificado:	mdc medical device certification GmbH
	Número de identificação	0483
☐ ANEXO I e II + III (categoria A, não-estéril)		
☐ Especificações comuns (GS):		
☒ Normas harmonizadas, normas nacionais, outros documentos normativos: ver anexo Lista de normas		

Prazo de validade da declaração de conformidade	**09.01.2029**

Em nome da MIKROGEN GmbH, gerente Dr. Erwin Soutschek:

i.V. [signature]	Neuried	28.08.2025
Assinatura	emitido em	Data

Dr. Eva Felder	QMB
Nom	Função

DoC_04_PT

Anexo Lista de normas

N.º do documento + estado da emissão	Título
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Podem ser acrescentadas linhas, se necessário

MIKROGEN DIAGNOSTIK

Declarație de conformitate UE

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Germania
SRN	DE-MF-000027747

Declarăm cu deplină răspundere că produsele enumerate mai jos corespund tuturor cerințelor aplicabile ale Regulamentului (UE) 2017/746 privind dispozitivele medicale pentru diagnostic *in vitro*.

Informații despre produs		
Denumire	**Cod UDI-DI de bază**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Clasificarea riscurilor (conform anexei VIII)

A ☐ B ☒ C ☐ D ☐

Procedura de evaluare a conformității

☒ ANEXA IX Sistem de calitate complet (Clasa B, C, D)	Nr. certificat UE:	D1060500064 in accordance with supplement D1060500065
	Organism notificat:	mdc medical device certification GmbH
	Nr. de identificare:	0483
☐ ANEXA IX Verificarea documentației tehnice (clasa D)	Nr. certificat UE:	
	Organism notificat:	mdc medical device certification GmbH
	Nr. de identificare:	0483
☐ ANEXA I și II + III (Clasa A, nesteril)		
☐ Specificații generale (SG):		
☒ Norme armonizate, norme naționale, alte documente normative: consultați anexa cu lista normelor		

Perioada de valabilitate a declarației de conformitate	**09.01.2029**

În numele MIKROGEN GmbH, Manager general Dr. Erwin Soutschek:

i.V. [signature] — Semnătură

Neuried — Publicat în

28.08.2025 — Data

Dr. Eva Felder — Num

QMB — Funcție

DoC_04_RO

Anexă cu lista normelor

Nr. document + număr versiune	Titlu
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

adăugați rânduri suplimentare dacă este necesar

Vyhlásenie o zhode EÚ

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Nemecko
SRN	DE-MF-000027747

Vo výlučnej zodpovednosti vyhlasujeme, že nižšie uvedené produkty zodpovedajú všetkým aplikovateľným požiadavkám nariadenia (EÚ) 2017/746 pre *in vitro* diagnostické pomôcky.

Informácie o produkte		
Názov	**Základný UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Klasifikácia rizika (podľa prílohy VIII)

A ☐ B ☒ C ☐ D ☐

Postup hodnotenia zhody

☒ PRÍLOHA IX Úplný systém kvality (trieda B, C, D)	Certifikát EÚ č.:	D1060500064 in accordance with supplement D1060500065
	Notifikovaná osoba:	mdc medical device certification GmbH
	Identifikačné číslo:	0483
☐ PRÍLOHA IX Kontrola technickej dokumentácie (trieda D)	Certifikát EÚ č.:	
	Notifikovaná osoba:	mdc medical device certification GmbH
	Identifikačné číslo:	0483
☐ PRÍLOHA I & II + III (trieda A, nesterilné)		
☐ Spoločné špecifikácie:		
☒ harmonizované normy, národné normy, ďalšie normatívne dokumenty: pozri prílohu zoznam noriem		

Doba platnosti vyhlásenia o zhode	**09.01.2029**

V mene spoločnosti MIKROGEN GmbH, riaditeľ Dr. Erwin Soutschek:

i.V. | Neuried | 28.08.2025

Podpis | vystavené v | Dátum

Dr. Eva Felder | QMB

Meno | Funkcia

DoC_04_SK

Príloha zoznam noriem

Č. dokumentu + stav vydania	Názov
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

v prípade potreby vložte ďalšie riadky

Izjava EU o skladnosti

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Nemčija
Enotna registrska številka (SRN)	**DE-MF-000027747**

Izključno na lastno odgovornost izjavljamo, da so spodaj navedeni izdelki v skladu z vsemi veljavnimi zahtevami Uredbe (EU) 2017/746 o *in vitro* diagnostičnih pripomočkih.

Informacije o izdelku		
Ime	**Osnovni UDI-DI**	**REF**
*recom*CLIA Control Set HEV IgG	04250571126050	75002

Razred tveganja (v skladu s Prilogo VIII)

A ☐ B ☒ C ☐ D ☐

Postopek ugotavljanja skladnosti

☒ PRILOGA IX Celovit sistem kakovosti (razred B, C, D)	Št. certifikata EU:	D1060500064 in accordance with supplement D1060500065
	Priglašeni organ:	mdc medical device certification GmbH
	Identifikacijska številka:	0483
☐ PRILOGA IX Pregled tehnične dokumentacije (razred D)	Št. certifikata EU:	
	Priglašeni organ:	mdc medical device certification GmbH
	Identifikacijska številka:	0483
☐ PRILOGA I & II + III (razred A, nesterilno)		
☐ Skupne specifikacije:		
☒ Usklajeni standardi, nacionalni standardi, drugi normativni dokumenti: glejte prilogo Seznam standardov		

Obdobje veljavnosti izjave EU o skladnosti	**09.01.2029**

V imenu podjetja MIKROGEN GmbH, direktor dr. Erwin Soutschek:

i.V. _____ Neuried _____ 28.08.2025

Podpis | Kraj | Datum

Dr. Eva Felder _____ QMB _____

Ime | Funkcija

Priloga Seznam standardov

Št. dokumenta + stanje izdaje	Naslov
EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011);
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019);
ISO/TR 24971:2020-06	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020).
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009);
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021);
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020);
EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022); German version EN ISO 18113-1:2024
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022); German version EN ISO 18113-2:2024
EN 62366-1:2015+AC:2015+AC:2016+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)

Po potrebi dodajte vrstice