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