

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
<i>recom</i> CLIA Sample Diluent A	42505711B2150WV	10120

Risk Classification (according Annex VIII)

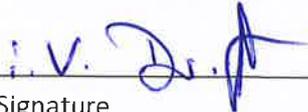
A B C D

Conformity Assessment Procedure

<input type="checkbox"/> ANNEX IX Full Quality System (Class B, C, D)	EU-Certificate #.:	
	Notified Body	mdc medical device certification GmbH
	Notified Body Identification:	0483
<input type="checkbox"/> ANNEX IX Technical Documentation Examination (Class D)	EU-Certificate #.:	
	Notified Body	mdc medical device certification GmbH
	Notified Body Identification:	0483
<input checked="" type="checkbox"/> ANNEX I & II + III (Class A, non-sterile)		
<input type="checkbox"/> Common Specifications (CS):		
<input checked="" type="checkbox"/> Harmonised standards, national standards, other normative documents: see annex list of standards		

Period of validity of the declaration of conformity	
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On behalf of MIKROGEN GmbH, Managing Director Dr. Erwin Soutschek:

 _____ Signature	Neuried _____ Issued in	03.06.2025 _____ Date
Dr. Eva Felder _____ Name	QMB _____ Function	

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 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 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 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 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-: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