

EU-Konformitätserklärung

EU Declaration of conformity

des Herstellers

of the manufacturer

Andreas Hettich GmbH & Co. KG • Föhrenstrasse 12 • D-78532 Tuttlingen • Germany
SRN: DE-MF-000010680

Hiermit erklären wir in unserer Verantwortung ohne Mitwirkung einer benannten Stelle, dass das bezeichnete Gerät:

We hereby declare under our responsibility without involvement of a notified body that the designated device:

Geräteart **Mikroliterzentrifuge**
Name **MIKRO 200**
MIKRO 200 R
Basic UDI-DI **040506740100109K**
GMDN **17452**
Klassifizierung **In-vitro-Diagnostikum, Klasse A**
(Anhang VIII, Regel 5)
Gemäß **Verordnung (EU) 2017/746**
Anhang IX

Type of device **microliter centrifuges**
Name **MIKRO 200**
MIKRO 200 R
Basic UDI-DI **040506740100109K**
GMDN **17452**
Classification **in vitro diagnostic, class A**
(Annex VIII, Rule 5)
according to **Regulation (EU) 2017/746**
Annex IX

inklusive des mit dem Gerät konformitätsbewerteten Zubehörs laut Zubehörliste der zugehörigen technischen Dokumentation, den einschlägigen Bestimmungen der Verordnung (EU) 2017/746 über In-vitro-Diagnostika entspricht.

and its accessories, which are listed in the related technical documentation and whose conformity has been assessed together with the device, complies with the relevant provisions of the Regulation (EU) 2017/746 on in vitro diagnostic devices.

Zweckbestimmung

Bei der Zentrifuge **MIKRO 200 / MIKRO 200 R** handelt es sich um ein In-vitro-Diagnostikum gemäß der Verordnung über In-vitro-Diagnostika (EU) 2017/746.

Intended use

The centrifuge **MIKRO 200 / MIKRO 200 R** is an in vitro diagnostic medical device according to the In vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

Das Gerät dient zum Zentrifugieren sowie zur Anreicherung von Probenmaterial menschlichen Ursprungs für eine anschließende Weiterverarbeitung für diagnostische Zwecke. Der Anwender kann jeweils die veränderbaren physikalischen Parameter innerhalb der vom Gerät vorgegebenen Grenzen einstellen.

The device is used for centrifuging and enriching sample material of human origin for subsequent further processing for diagnostic purposes. The user can set each of the variable physical parameters within the limits set by the device.

Die Zentrifuge darf nur von Fachpersonal in geschlossenen Laboratorien verwendet werden. Die Zentrifuge ist nur für den oben genannten Verwendungszweck bestimmt. Zur bestimmungsgemäßen Verwendung gehört auch das Beachten aller Hinweise aus der Bedienungsanleitung und die Einhaltung der Inspektions- und Wartungsarbeiten.

The centrifuge may only be used by qualified personnel in closed laboratories. The centrifuge is only intended for the use referred to above. Intended use also includes observing all instructions in the Operating Manual and compliance with the required inspection and maintenance work.

Eine andere oder darüberhinausgehende Benutzung gilt als nicht bestimmungsgemäß. Für hieraus entstehende Schäden haftet die Firma Andreas Hettich GmbH & Co. KG nicht.

Das Gerät entspricht auch den anwendbaren Bestimmungen der folgenden europäischen Richtlinien und Verordnungen

- 2006/42/EG „Maschinenrichtlinie“
- 2014/30/EU „EMV-Richtlinie“
- 2014/35/EU „Niederspannungsrichtlinie“
- 2011/65/EG „RoHS-Richtlinie“
(ohne Beteiligung einer benannten Stelle)
- (EG) 1907/2006 „REACH Verordnung“
(ohne Beteiligung einer benannten Stelle)

Angewandte Normen:

Siehe Liste der angewandten Normen, die Teil der technischen Dokumentation ist

Any other use or use beyond this is considered improper. Andreas Hettich GmbH & Co. KG shall not be liable for any damage arising from this.

The device also complies to the applicable provisions of the following European directives, ordinances and standards

- 2006/42/EC "Directive on machinery"
- 2014/30/EU "EMC Directive"
- 2014/35/EU „Low Voltage Directive“
- 2011/65/EC "RoHS Directive"
(without involvement of a notified body)
- (EC) 1907/2006 „Regulation on REACH“
(without involvement of a notified body)

Standards applied:

See the list of applied standards that forms part of the technical documentation.

Tuttlingen, 30.10.2023



Klaus-Günter Eberle
Geschäftsführer, Chief Executive Officer



Diese Konformitätserklärung ist gültig von 30.10.2023 bis 24.10.2025

This declaration of conformity is valid from 30.10.2023 until 24.10.2025

Certificate

mdc medical device certification GmbH
certifies that

Hettich

Andreas Hettich GmbH & Co. KG
Föhrenstraße 12
78532 Tuttlingen
Germany

for the scope

**Design, development, manufacturing, distribution and servicing of
laboratory centrifuges for IVD applications and general laboratory use,
centrifuges for separation of blood components for transfusion purposes and
microbiological incubators for IVD applications and general laboratory use**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-10-25
Valid until	2025-10-24
Registration no.	D1459300003
Report no.	P21-01967-222238
Stuttgart	2022-10-25



Head of Certification Body





Management Service

CERTIFICATE

Certificate Registration No.: 12 100/104 59604 TMS / Order No.: 707111087

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

Hettich

Andreas Hettich GmbH & Co. KG

Föhrenstr. 12
78532 Tuttlingen
Germany

for the scope

**Development, production and distribution of
laboratory equipment, accessories, spare parts with the associated services**

including the sites see enclosure

has established and applies
a Quality and Environmental Management System.

Performance of audits has furnished proof that these
management systems meet the requirements of the following standards:

**DIN EN ISO 9001:2015
DIN EN ISO 14001:2015**

The certificate is valid from **2024-06-10** until **2027-05-25**.

Fred Wenke
Head of Certification Body
Munich, 2024-05-24

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Management Service

ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100/104 59604 TMS / Order No.: 707111087

certificate holder:

Andreas Hettich GmbH & Co. KG
Föhrenstr. 12
78532 Tuttlingen
Germany

at the sites	scope
Andreas Hettich GmbH & Co. KG Föhrenstr. 12 78532 Tuttlingen Germany	Development, production and distribution of laboratory equipment, accessories, spare parts with the associated services
Andreas Hettich GmbH & Co. KG Föhrenstraße 25 78532 Tuttlingen Germany	Inspection and repair of returned goods and customer goods

Fred Wenke
Head of Certification Body
Munich, 2024-05-24



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CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

MICROLITRE CENTRIFUGES

— MIKRO 200 | 200 R

FASTER RESULTS IN MOLECULAR BIOLOGY

The MIKRO 200 are amongst the highest-speed microliter centrifuges in their class. Rotors are designed to spin microliter and PCR tubes. MIKRO 200 achieves a maximum RCF of 21,382 with up to 30 tubes, enabling rapid processing of samples and optimal separation, at low noise levels of 54 dB(A).

This unit is available with refrigeration and a temperature range from -10 °C to +40 °C (MIKRO 200 R).



— HIGHLIGHTS

- RPM: 500 - 15,000 min⁻¹
Adjustable in increments of 10
- max. RCF: 21,382
- max. capacity: 30 x 2.0 ml
- Choice of 4 rotors
- IVDR-conform according to regulation (EU) 2017/746
- impulse key for short cycle mode
- easy operation with keypad and control knob
- 4 program memories for more individuality
- 9 individual acceleration and deceleration stages
- model 200 R coolable from -20 to +40 °C with pre-cooling function

— FEATURES





- metal housing and lid
- viewing port in the lid
- powered one-hand lid lock
- lid dropping protection
- emergency lid lock release
- stainless steel chamber
- automatic rotor recognition
- brushless drive
- error display
- display in °C and °F possible
- imbalance switch-off
- backlit panel with actual values of all parameters
- audio message after completion of the centrifugation run

TECHNICAL DATA

	MIKRO 200 non-refrigerated	MIKRO 200 R refrigerated
voltage *)	200 – 240 V 1 ~	200 – 240 V 1 ~
frequency	50 – 60 Hz	50 Hz
consumption	240 VA	450 VA
emission, immunity	EN/IEC 61326-1, class B	EN/IEC 61326-1, class B
max. capacity	30 x 1.5 / 2.0 ml	30 x 1.5 / 2.0 ml
max. RPM	15,000 min ⁻¹	15,000 min ⁻¹
max. RCF	21,382	21,382
running time	1 – 99 min: 59 s, ∞ continuous run, short cycle mode (impulse button)	1 – 99 min: 59 s, ∞ continuous run, short cycle mode (impulse button)
dimensions (WxDxH)	275 x 344 x 260 mm	281 x 553 x 260 mm
weight	approx. 11.5 kg	approx. 28 kg
noise level	≤ 58 dB (A) with rotor 2434	≤ 51 dB (A) with rotor 2437
temperature control, infinitely variable	-	from -10 to +40 °C
Cat. No.	2400	2405
100 – 127 V 1 ~ / 50–60 Hz	2400-01	2405-01
consumption	270 VA	630 VA
emission, immunity	FCC class B	FCC class B

*) Other voltages on request.

AVAILABLE ROTORS

ANGLE ROTORS	angle	max. RPM	max. capacity	Cat. No.	page
 angle rotor, 24-place	45°	15,000 min ⁻¹	24 x 2 ml	2434	3
 angle rotor, 30-place	45° inside / 55° outside	15,000 min ⁻¹	30 x 2 ml	2437	3
 angle rotor, 24-place for spin column kits	45°	15,000 min ⁻¹	24 x 2 ml	2428	4
 angle rotor, 4-place	45°	15,000 min ⁻¹	4 x 8 PCR strips	2418-A	4

— ANGLE ROTOR, 24-PLACE | 2434



Rotor	
max. RPM max. RCF	15,000 min ⁻¹ 21,382
max. capacity	24 x 2 ml
run up run down, braked in sec	20 28
angle max. noise level	45° 53 dB (A)
temperature in °C ¹⁾	+4
Cat. No.	2434



Lid bioseal⁹⁾	
Cat. No.	INCLUSIVE



Vessels							
capacity in ml	0.2	0.4	0.5	0.8	1.5	2.0	0.5
Ø x L in mm	6 x 18	6 x 45	8 x 30	8 x 45	11 x 38	11 x 38	10.7 x 46
max. RCF ²⁾	21,382	21,382	21,382	21,382	21,382	21,382	20,376
radius in mm	85	85	85	85	85	85	81
Cat. No.	microliter tubes						Pediatric



Adapter							
boring Ø x L in mm	6 x 40	6 x 40	8 x 40	8 x 40	10,2 x 19,3	11,2 x 42,6	11,2 x 39
vessels per rotor	24	24	24	24	24	24	12
Cat. No.	2024	2024	2023	2023	2031⁷⁾	-	0788

— ANGLE ROTOR, 30-PLACE | 2437



Rotor	
max. RPM max. RCF	15,000 min ⁻¹ 21,382
max. capacity	30 x 2 ml
run up run down, braked in sec	22 30
angle max. noise level	45° inside / 55° outside 51 dB (A)
temperature in °C ¹⁾	+4
Cat. No.	2437



Lid bioseal⁹⁾	
Cat. No.	INCLUSIVE



Vessels							
capacity in ml	0.2	0.4	0.5	0.8	1.5	2.0	0.5
Ø x L in mm	6 x 18	6 x 45	8 x 30	8 x 45	11 x 38	11 x 38	10.7 x 46
max. RCF ²⁾	21,382	21,382	21,382	21,382	21,382	21,382	20,376
radius in mm	85	85	85	85	85	85	81
Cat. No.	microliter tubes						Pediatric



Adapter							
boring Ø x L in mm	6 x 40	6 x 40	8 x 40	8 x 40	10,2 x 19,3	11,2 x 41,3	11,2 x 39
vessels per rotor	30	30	30	30	30	30	15
Cat. No.	2024	2024	2023	2023	2031⁷⁾	-	0788

- 1) For cooled versions: Lowest temperature achievable with precooling and max. speed.
- 2) Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers.
- 5) Tested by the TÜV in conformity with DIN EN 61010, section 2 - 020.
- 7) For centrifugation at high speeds, we recommend to use conical, phenol-resistant adapters. Cat. No. 2031.

— ANGLE ROTOR, 24-PLACE | 2428



Rotor	
max. RPM max. RCF	15,000 min ⁻¹ 21,382
max. capacity	24 x 2 ml
run up run down, braked in sec	20 28
angle max. noise level	45° 53 dB (A)
temperature in °C ¹⁾	+4
Cat. No.	2428



Lid bioseal⁵⁾	
Cat. No.	INCLUSIVE



Vessels

capacity in ml	0.2	0.4	0.5	0.8	1.5	2.0	1.5	2.0	0.5
Ø x L in mm	6x18	6 x 45	8 x 30	8x45	11x38	11x38	11x38	11x38	10.7 x 46
max. RCF ²⁾	21,382	21,382	21,382	21,382	21,382	21,382	21,382	21,382	20,376
radius in mm	85	85	85	85	85	85	85	85	81
Cat. No.	microliter tubes						micro spin columns		Pediatric



Adapter

boring Ø x L in mm	6 x 40	6 x 40	8 x 40	8 x 40	10,2 x 19,3	10,2 x 19	10,2 x 19,3	11,2 x 42,6	11,2 x 39
vessels per rotor	24	24	24	24	24	24	24	24	12
Cat. No.	2024	2024	2023	2023	2031⁷⁾	-	2031⁷⁾	-	0788

— ANGLE ROTOR, 4-PLACE | 2418-A



Rotor	
max. RPM max. RCF	15,000 min ⁻¹ 14,338
max. capacity	4 x 8 PCR strips
run up run down, braked in sec	19 28
angle	45°
temperature in °C ¹⁾	+4
Cat. No.	2418-A



Lid	
Cat. No.	E3243



Vessels

capacity in ml	0.2	0.2
Ø x L in mm	6x18	-
max. RCF ²⁾	14,338	14,338
radius in mm	57	57
Cat. No.	-	PCR strips



Adapter

boring Ø x L in mm	6,5 x 15,5	6,5 x 15,5
vessels per rotor	32	4 x 8
Cat. No.	-	-

- 1) For cooled versions: Lowest temperature achievable with precooling and max. speed.
- 2) Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers.
- 5) Tested by the TÜV in conformity with DIN EN 61010, section 2 - 020.
- 7) For centrifugation at high speeds, we recommend to use conical, phenol-resistant adapters. Cat. No. 2031.

CERTIFICATIONS / REGISTRATIONS

Product certification:



Product registration:

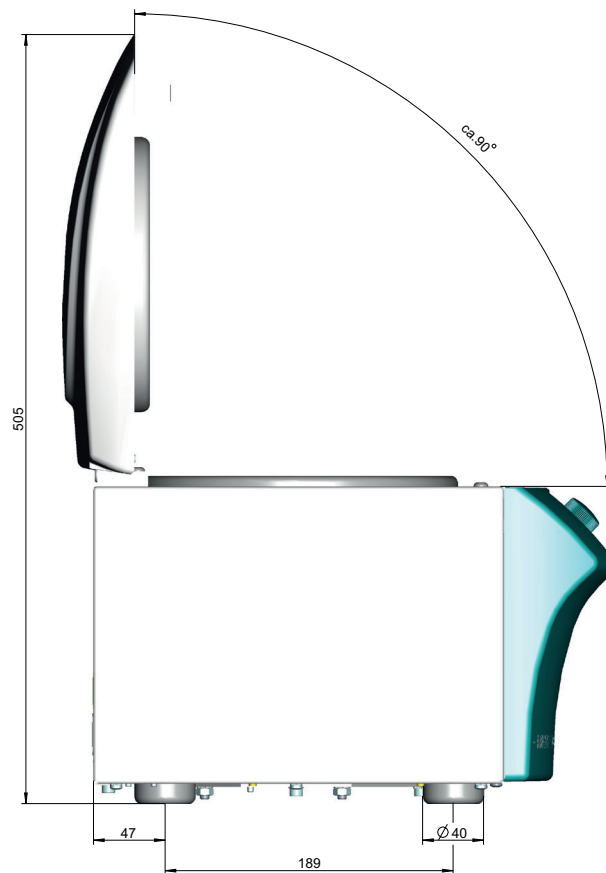


according to regulation (EU) 2017/746

Company certifications:



DIMENSIONS – MIKRO 200



— DIMENSIONS – MIKRO 200 R

