Anexa 13 Centrifuga MIKRO 200R, cu rotor 2428

Specificarea tehnică deplină solicitată, Standarde de referinţă	Specificarea tehnică deplină oferita, Standarde de referinţă
Centrifugă de laborator cu răcire (24 tuburi) Descriere Centrifugele de laborator sunt concepute pentru a centrifuga sângele. Parametrul Specificaţia Viteza de rotaţie Minimală, rpm reglabilă Maximală, rpm ≥1500 Setări setarea vitezei Capacitatea Tipul tuburilor tuburi de 1,5 - 2,0 ml Numărul de tuburi rotor unghiular ≥ 24 de tuburi Timer Diapazon minim de timp 1 - ≥ 99 min functionare continuă, mod ciclu scurt (buton impuls) obligatoriu Incrementarea ≤ 1 min Refrigerare obligatoriu interval de temperatură de la -10 ^{0}C la +40 ^{0}C Securitatea Blocarea capacului în timpul lucrului obligatoriu Indicatori Indicarori vizual şi acustic obligatoriu Debalansare obligatoriu Pornire/oprire obligatoriu Capac deschis obligatoriu Display Digital obligatoriu Nivelul de zgomot ≤ 60 dB obligatoriu Fereastra, orificiu sau alt acces, necesar pentru efectuarea procedurii de verificare periodică, conform normelor şi standardelor în vigoare obligatoriu	Centrifugă de laborator cu răcire (24 tuburi) Descriere Centrifugele de laborator sunt concepute pentru a centrifuga sângele. Parametrul Specificaţia Viteza de rotaţie Minimală, rpm reglabilă – 500 rpm Maximală, rpm 15 000 Setări setarea vitezei in diapason 500-15000 rpm Capacitatea Tipul tuburilor tuburi de 1,5 - 2,0 ml. rotor propus 2428 Numărul de tuburi rotor unghiular ≥ 24 de tuburi Timer Diapazon minim de timp 1 - ≥ 99 min si 59 secunde, sau continuu functionare continuă, mod ciclu scurt (buton impuls) obligatoriu Incrementarea 1 min Refrigerare obligatoriu interval de temperatură de la -10 ^{0}C la +40 ^{0}C, cu functie de precooling Securitatea Blocarea capacului în timpul lucrului obligatoriu Indicatori Indicarori vizual şi acustic obligatoriu Debalansare obligatoriu Pornire/oprire obligatoriu Capac deschis obligatoriu Display Digital obligatoriu Nivelul de zgomot 51 dB obligatoriu Fereastra transparenta, necesara pentru efectuarea procedurii de verificare periodică, conform normelor şi standardelor în vigoare obligatoriu

Microlitre centrifuge

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)
dimesions (W x D x H)	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 I max. RCF	15,000 min^{-1} I 21,382
max. capactiy	24 x 2 ml
run up I run down, braked in sec	20 I 28
angle I max. noise level	45° I 53 dB (A)
temperature in °C[1]	+4
Cat. No.	**2434**

Lid bioseal [5]	
Cat. No.	**INCLUSIVE**

	microliter tubes						Pediatric
Vessels							
capacity in ml	0.2	0.4	0.5	0.8	1.5	2.0	0.5
Ø x L in mm	6x18	6 x 45	8 x 30	8x45	11x38	11x38	10.7x46
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
Adapter							
boring Ø x L in mm	6 x 40	6 x 40	8 x 40	8 x 40	10,2 x 19,3	11.2x42.6	11.2 x 39
vessels per rotor	24	24	24	24	24	24	12
Cat. No.	**2024**	**2024**	**2023**	**2023**	**2031[7]**	**-**	**0788**

Angle rotor, 30-place | 2437

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

Lid bioseal [5]	
Cat. No.	**INCLUSIVE**

	microliter tubes						Pediatric
Vessels							
capacity in ml	0.2	0.4	0.5	0.8	1.5	2.0	0.5
Ø x L in mm	6x18	6 x 45	8 x 30	8x45	11x38	11x38	10.7x46
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
Adapter							
boring Ø x L in mm	6 x 40	6 x 40	8 x 40	8 x 40	10,2 x 19,3	11.2x41.3	11.2x39
vessels per rotor	30	30	30	30	30	30	15
Cat. No.	**2024**	**2024**	**2023**	**2023**	**2031[7]**	**-**	**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 I max. RCF	15,000 min^{-1} I 21,382
max. capactiy	24 x 2 ml
run up I run down, braked in sec	20 I 28
angle I max. noise level	45° I 53 dB (A)
temperature in °C[1]	+4
Cat. No.	**2428**

+

Lid bioseal [5]	
Cat. No.	**INCLUSIVE**

	microliter tubes						micro spin columns		Pediatric
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	10.7x46
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
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	11.2x42.6	11.2 x 39
vessels per rotor	24	24	24	24	24	24	24	24	12
Cat. No.	**2024**	**2024**	**2023**	**2023**	**2031 [7]**	**-**	**2031 [7]**	**-**	**0788**

Angle rotor, 4-place | 2418-A

Rotor	
max. RPM I max. RCF	15,000 min^{-1} I 14,338
max. capactiy	4 x 8 PCR strips
run up I run down, braked in sec	19 I 28
angle	45°
temperature in °C[1]	+4
Cat. No.	**2418-A**

+

Lid	
Cat. No.	**E3243**

	-	PCR strips
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
Adapter		
boring Ø x L in mm	6.5x15.5	6.5x15.5
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.

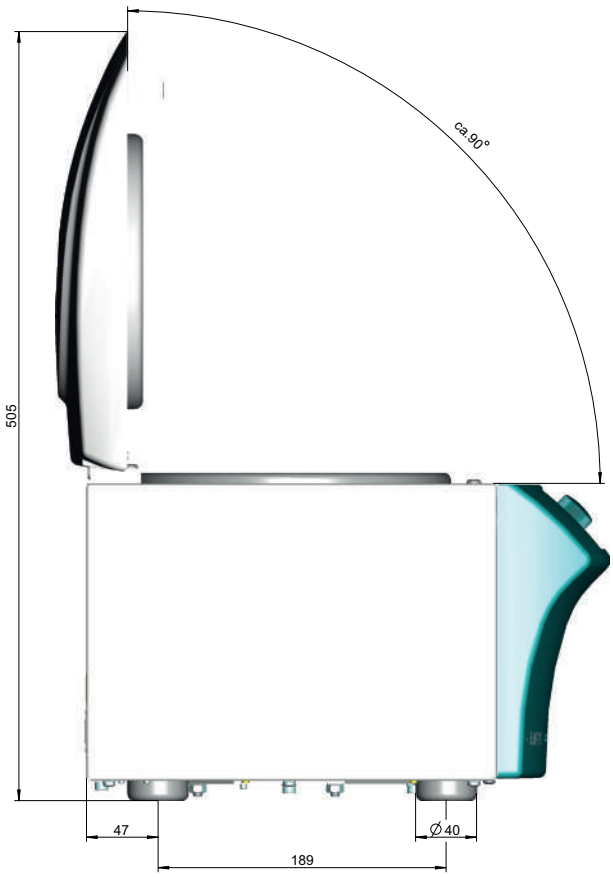
Certifications / Registrations

Product certification:

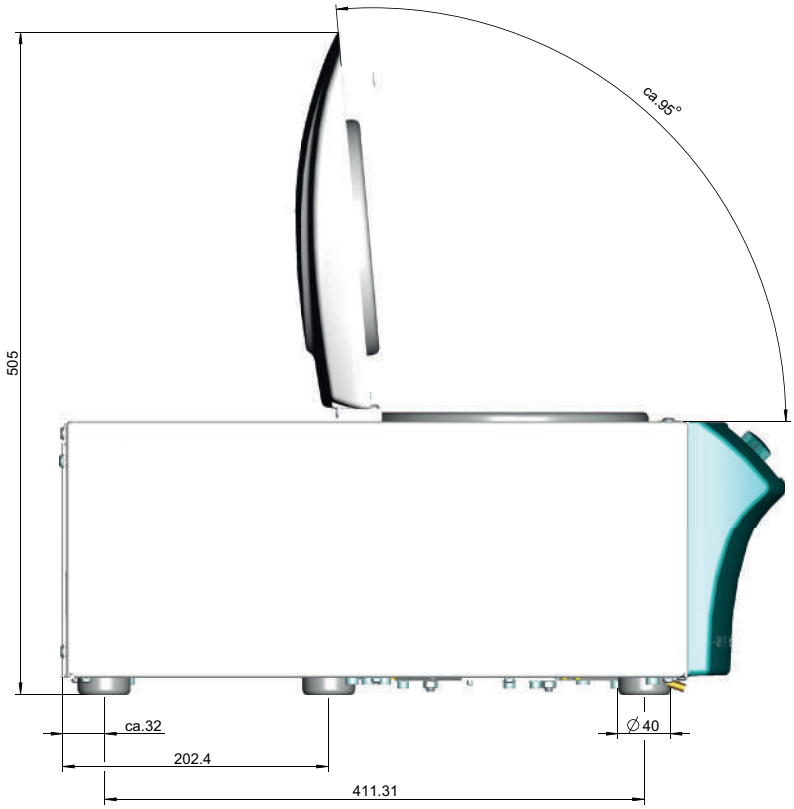
Product registration:

Company certifications:

Dimensions – MIKRO 200



Dimensions – MIKRO 200 R



DS.0525-EN

Andreas Hettich GmbH
Föhrenstr. 12
78532 Tuttlingen
Germany

info@hettichlab.com
Phone 07461 705-0

Operating instructions

MIKRO 200 / 200 R

Translation of the original operating instructions

Andreas Hettich GmbH

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Internet: www.hettichlab.com

Table of contents

1 About this document

1.1 Use of this document

- Read this document carefully and in full before commissioning the device for the first time.
  Observe other enclosed instruction sheets where necessary.
- This document is part of the device and must be kept within easy reach.
- This document must be included if the device is passed on to a third party.
- The current version of the document in the available languages can be found on the manufacturer's website: ➦ *https://www.hettichlab.com/de/download-center/*

1.2 Gender reference

The employed masculine or feminine language form is to facilitate reading. In the spirit of equal treatment, corresponding terms apply in principle to all genders and do not imply any valuation.

1.3 Symbols and labels in this document

General symbols

The following markers are used in this document to highlight instructions, results, listings, references and other elements:

Marker	Explanation
1. ➥ 2. ➥ 3. ➥ ... ➥	Step-by-step instructions
➡	Results of action steps
➦	References to sections of the document and other applicable documents
■ ... ■ ...	Listings without a fixed order
[Buttons]	Controls (for example: buttons, switches)
'Indicator'	Indicator elements (for example: signal lights, screen elements)

2 Safety

2.1 Intended use

Intended use

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

The device is used to separate samples of human origin into their constituent parts for subsequent further processing. The user can set each of the variable physical parameters within the limits set by the device.

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 user manual and compliance with inspection and maintenance. Any other use or use beyond this scope is considered improper. Andreas Hettich GmbH shall not be liable for any damage arising from such non-compliant use.

Non-intended use

- The centrifuge is not suitable for use in explosive or radioactive, or biologically or chemically-contaminated atmospheres.
- The user must take appropriate actions when centrifuging hazardous substances or mixtures of substances that are toxic, radioactive or contaminated with pathogenic microorganisms.

  The manufacturer generally recommends using only centrifuge tubes with special screw caps designed for use with hazardous substances.

  Use sealable centrifuge tubes with a biosafety system for materials of risk groups 3 and 4.
- The manufacturer does not recommend centrifugation of flammable or explosive materials.
- The manufacturer does not recommend centrifugation of materials that react chemically with one another with high activation energy.

Foreseeable misuse

The manufacturer recommends using only accessories approved that it has approved for the intended purpose.

Only operate the centrifuge under supervision.

2.2 Personnel requirements

Required qualifications

The user has read the Operating Manual in full and familiarised themselves with the device.

NOTICE

Damage to the device by unauthorised personnel

– Tampering with and modifications to devices by unauthorised persons are at the operating organisation's own risk and will result in the loss of all warranty and liability claims.

Trained user

The user has been educated and trained in laboratory work and is able to carry out the work assigned to them, and to recognise and prevent potential hazards independently.

Personal protective equipment

Lack of personal protective equipment or unsuitable personal protective equipment increases the risk of impaired health and injury.

- Only use personal protective equipment that is in proper condition.
- Only use personal protective equipment that is adapted to the person (correct size, for example).
- Observe instructions on other protective equipment for specific activities.

2.3 Operator's responsibility

Follow the instructions in this document for proper and safe use of the device.

Keep the user manual for future reference.

Provide information

- Following the instructions in this document will help:
  - To avoid dangerous situations.
  - To minimise repair costs and downtime.
  - To increase the reliability and service life of the device.
- The operator is responsible for compliance with company regulations, standards and national laws.
- Note and keep the revision of the document separate from the document. If lost, the document can be replaced in the correct revision.
- Keep the user manual available at the place where the device is used.
- Pass the user manual on to the buyer when the device is sold.

Personnel training

Lack of knowledge when working with the device may result in serious injury or death.

- Instruct personnel on their tasks and the associated risks in accordance with the instruction.

2.4 Safety instructions

Reporting of events and incidents

In the event of incidents or notifiable events involving the device or its accessories, these must be reported to the manufacturer and, where applicable, to the competent authority where the user and/or the patient is registered.

Manufacturer:

Andreas Hettich GmbH

Föhrenstrasse 12

78532 Tuttlingen, Germany

Phone: +49 7461 705 0

E-mail: info@hettichlab.com

DANGER

Risk of contamination

Inadequate cleaning or failure to observe the cleaning instructions can lead to contamination risks.

- Observe national and local regulations on safety and accident prevention.
- Observe cleaning instructions.
- Wear personal protective equipment when cleaning the device.
- Comply with laboratory regulations (e.g. TRBAs, the German Protection against Infection Act, hygiene plan) for handling biological agents.

DANGER

Risk of fire and explosion

Risk of accidents, injuries or damage to property due to fire or explosion.

- Observe regulations and directives for handling chemicals and hazardous substances.
- Do not use corrosive chemicals.
- Do not use dangerous chemicals.
- Do not use corrosive extraction agents.
- Do not use strong acids.

WARNING

Risk of injury

Inadequate or late maintenance can result in injuries.

- Observe maintenance intervals.
- Check the device for visible damage or defects.
  If any visible damage or defects are present, immediately remove the device from service and inform a service technician.

WARNING

Risk of electric shock

Liquids that penetrate the device may cause electric shocks.

- The device must be protected from external contact with liquids.
- Do not pour any liquids inside the device.
- The original transport packaging must be used when transporting the device.

WARNING

Contamination with hazardous substances and substance mixtures

Observe the following actions for substances and substance mixtures that are toxic, radioactive and/or contaminated with pathogenic microorganisms:

- As a rule, use only centrifuge tubes with special screw caps for hazardous substances.
- Use sealable centrifuge tubes with a biosafety system for materials of risk groups 3 and 4.
- If no biosafety system is used, the device is not microbiologically tight in the sense of standard EN / IEC 61010-2-020.
- Contact the manufacturer if necessary.

WARNING

Risk of injury and device damage due to the rotor

A loose rotor can cause injuries and device damage.

- Check that the rotor is firmly seated.
- Follow maintenance intervals.

CAUTION

Risk of injury

Long hair and clothing can get caught in the rotor during manual movement.

- Tie long hair back.
- Do not allow garments to hang in the centrifuging chamber.

NOTICE

Damage

Incorrect voltage or frequency.

- Only operate the device according to the specifications on the rating plate.
  Compliance with the instructions for use.

NOTICE

Damage

Aborting the program early can cause damage to the device and samples.

- Do not switch off, perform an emergency release or pull out the mains plug.

3 Device overview

3.1 Technical data

Manufacturer	Andreas Hettich GmbH D-78532 Tuttlingen	
Model	MIKRO 200	
Type	2400	2400-01
Mains voltage (±10%)	200-240 V 1~	110-127 V 1~
Mains frequency	50-60 Hz	50-60 Hz
power consumption	240 VA	270 VA
Power consumption	1.2 A	2.7 A
max. capacity	30 x 2.0 ml	
max. permissible density	1.2 kg/dm³	

max. speed (RPM)	15000		
max. acceleration (RCF)	21382		
max. kinetic energy	5800 Nm		
Obligation to perform checks (DGUV Rules 100-500) (valid only in Germany)	No		
Ambient conditions (EN / IEC 61010-1):			
Installation site	indoors only		
Altitude	up to 2000 m above sea level		
Ambient temperature	2 °C to 40 °C		
Humidity	maximum relative humidity 80% for temperatures up to 31 °C, decreasing linearly to 50% relative humidity at 40 °C.		
Overvoltage category (IEC 60364-4-443)	II		
Pollution level	2		
Device protection class	I not suitable for use in potentially explosive atmospheres.		
EMC:			
Emitted EM interference, EM interference immunity	EN / IEC 61326-1 Class B	FCC Class B	
Noise level (rotor-dependent)	≤58 dB(A)		
Dimensions:			
Width	275 mm		
Depth	344 mm		
Altitude	260 mm		
Weight	approx. 11.5 kg		
Manufacturer	Andreas Hettich GmbH D-78532 Tuttlingen		
Model	MIKRO 200 R		
Type	2405	2405-07	2405-01
Mains voltage (±10%)	200-240 V 1~	200-240 V 1~	110-127 V 1~

Mains frequency	50 Hz	60 Hz	50-60 Hz
power consumption	450 VA	2450 VA	630 VA
Power consumption	1.9 A	2.0 A	5.0 A
Refrigerant	R134a		
max. capacity	30 x 2.0 ml		
max. permissible density	1.2 kg/dm³		
max. speed (RPM)	15000		
max. acceleration (RCF)	21382		
max. kinetic energy	5800 Nm		
Obligation to perform checks (DGUV Rules 100-500) (valid only in Germany)	No		
Ambient conditions (EN / IEC 61010-1):			
Installation site	indoors only		
Altitude	up to 2000 m above sea level		
Ambient temperature	5 °C to 35 °C		
Humidity	maximum relative humidity 80% for temperatures up to 31 °C, decreasing linearly to 50% relative humidity at 40 °C.		
IP ratings	IP 20		
Overvoltage category (IEC 60364-4-443)	II		
Pollution level	2		
Device protection class	I not suitable for use in potentially explosive atmospheres.		
EMC:			
Emitted EM interference, EM interference immunity	EN / IEC 61326-1, Class B		FCC Class B
Noise level (rotor-dependent)	≤53 dB(A)	≤54 dB(A)	
Dimensions:			
Width	281 mm		
Depth	553 mm		

Altitude	260 mm
Weight	approx. 28 kg

Rating plate

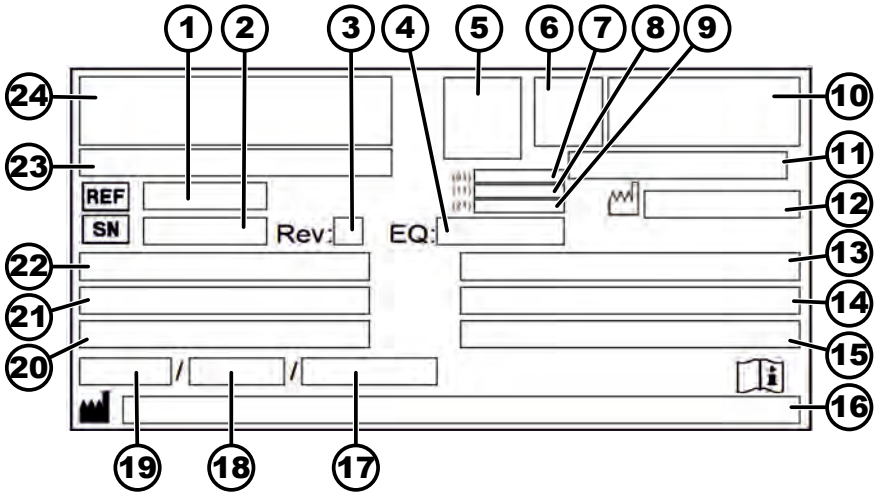


Fig. 1: Rating plate

1 Item number
2 Serial number
3 Revision
4 Equipment number
5 Data matrix code
6 any labelling indicating whether medical device or in vitro diagnostic medical device
7 Global Trade Item Number (GTIN)
8 Date of manufacture
9 Serial number
10 any EAC mark, CE mark
11 Country of manufacture
12 Date of manufacture
13 Mains frequency
14 Maximum kinetic energy
15 Maximum permissible density
16 Manufacturer's address
17 any Coolant circuit pressure
18 any Coolant capacity
19 any Coolant type
20 Revs per minute
21 Performance values
22 Mains voltage
23 any Device designation
24 Manufacturer's logo

3.2 Certifications and logos

Certifications

ISO 9001

Quality management system in accordance with ISO 9001

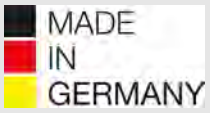
ISO 14001

Environmental management in accordance with ISO 14001

EN ISO 13485

Quality management in accordance with ISO 13485

Logos



Made in Germany

Device was developed and made in Germany.

3.3 European registration

Device conformity

Device conformity according to EU directives.

CE

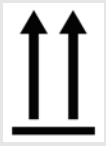
Single Registration Number

SRN: DE-MF-000010680

Basic-UDI-DI

Basic-UDI-DI	Device assignment
040506740100109K	MIKRO 200 / 200 R (in vitro diagnostic medical device)

3.4 Important labels on the packaging



TOP

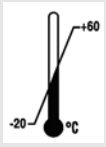
This is the correct upright position of the shipping container for transport and/or storage.

FRAGILE GOODS

The contents of the shipping container are fragile, so it must be handled with care.

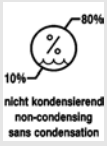
PROTECT FROM MOISTURE

Protect the transport packaging from moisture and keep it in a dry environment.



TEMPERATURE LIMITATION

The shipping container must be stored, transported and handled within the indicated temperature range (-20 °C to +60 °C).



HUMIDITY LIMITATION

The shipping container must be stored, transported and handled within the indicated air humidity range (10 % to 80 %, non-condensing).

STACK LIMITATION BASED ON QUANTITY

Maximum number of identical packages that may be stacked on the lowest package, "n" standing for the number of packages allowed. The lowest package is not included in "n".

3.5 Important labels on the device

The signs on the device must not be removed or covered, or have anything pasted over them.

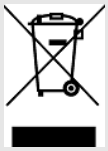
Attention, general danger area.

Ensure you read the instructions for commissioning and operation and observe the safety instructions before using the device.

Biohazard warning.

Direction of rotation of the rotor.

The orientation of the arrow indicates the rotor's direction of rotation.



Symbol for the separate collection of electrical and electronic equipment, in accordance with Directive 2012/19/EU (WEEE).

Use in European Union countries, Norway and Switzerland.

3.6 Operating and indicator elements

3.6.1 Control

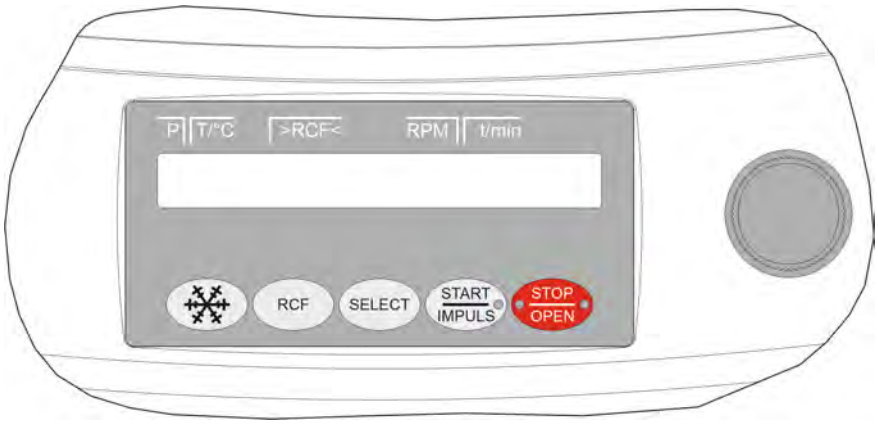


Fig. 2: Control (device with cooling)

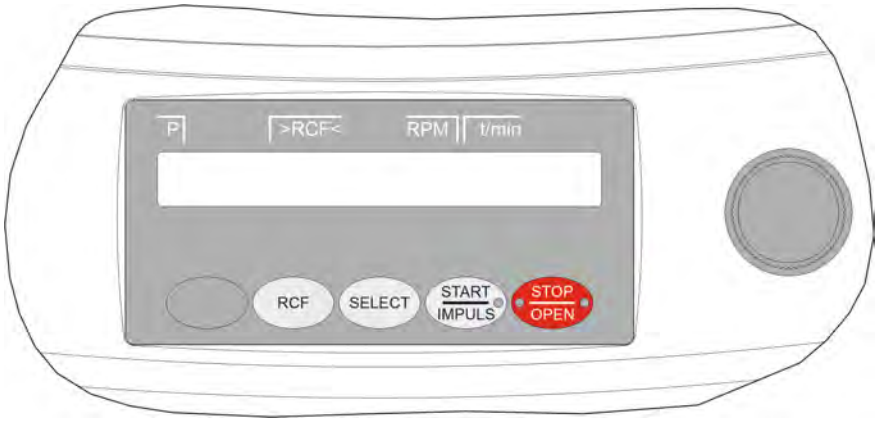


Fig. 3: Control (device without cooling)

3.6.2 Indicator elements

Fig. 4: [START/IMPULS] button

- The button lights up during the centrifugation run for as long as the rotor is not yet at a standstill.

Fig. 5: [STOP/OPEN] button

- The right side of the button lights up when the centrifuge is in ramp-down. The rotor has not yet stopped.
- The left side of the button lights up when the rotor is stationary.
- The light on the left side of the button goes out when the lid is unlocked.

3.6.3 Controls

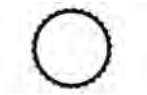


Fig. 6: [Rotary knob]

- Setting the individual parameters.
  Turning anticlockwise decreases the value.
  Turning clockwise increases the value.

Fig. 7: [Mains switch]

- Switch the device on and off.

Fig. 8: [Cooling] button

- Start the centrifugation run to pre-cool the rotor (only for centrifuges with cooling).
- The precooling speed is adjustable. The default value is 10,000 RPM.

Fig. 9: [RCF] button

- Toggle between RCF indicator and RPM indicator.
- Relative centrifugal force, RCF.
  The RCF is displayed in brackets ⟩ ⟨.
- Speed, RPM.

Fig. 10: [SELECT] button

- Selecting the individual parameters.
- Scroll forward in the menus.

Fig. 11: [START/IMPULSE] button

- Start centrifugation run.
- Short-term centrifugation. The centrifugation run takes place as long as the button is being pressed.
- Save entries and changes.

Fig. 12: [STOP/OPEN] button

- End the centrifugation run.
  The rotor coasts to a stop with the preselected ramp-down parameter.
- Pressing the button twice triggers the quick stop function.
- Unlock the lid.
- Exit parameter input and the menus.

3.7 Original spare parts

Use only original spare parts from the manufacturer and approved accessories.

3.8 Scope of delivery

The following accessories are supplied with the centrifuge:

- 1 hex key (SW5 x 100)
- 1 right-angled hex key (2.5 mm)
- 2 Fuse link

- 1 power cable
- 1 user manual
- 1 instruction sheet, transport lock

Rotors and the corresponding accessories are supplied depending on the order.

3.9 Returns

An original Return Material Authorisation (RMA) form from the manufacturer must always be requested for a return. Secure and reliable acceptance and booking in of the goods with the manufacturer is not possible without an original RMA form from the manufacturer. The Return Material Authorisation (RMA) form contains a Declaration of No Objection (UBE), which must be completed in full and enclosed with the return.

If the device and/or accessories are returned to the manufacturer, the complete return shipment must be cleaned and decontaminated by the sender. If returns are not cleaned and/or decontaminated or are insufficiently cleaned and/or decontaminated, this will be performed by the manufacturer and charged to the sender.

The original transport locks must be attached for return shipment, see ➦ *Chapter 4 'Transport and storage' on page 17*. The device must be shipped in its original packaging.

4 Transport and storage

4.1 Transport and storage conditions

Transport conditions

NOTICE

Damage

The device may be damaged if it is not secured during transport.

- Secure the transport locks before transport.
- Observe the transport instructions.

NOTICE

Danger due to condensation in the event of temperature differences

Moisture may damage electrical components.

- Ensure that all surfaces are dry prior to commissioning or maintenance.
- If the temperature changes, wait until the device or component has become acclimatised.
- Prevent moisture from penetrating into sensitive components.
- If moisture forms, switch off the device immediately and allow it to dry properly.

- Before transporting, fasten the transport lock and disconnect the device from the mains socket.
- The transport temperature must be between -20 °C and +60 °C.
- Humidity must not be condensing. Humidity must be between 10% and 80%.
- Be aware of the weight of the device.
- When transporting using a transport aid (e.g., a pallet truck), the transport aid must be able to carry at least 1.6 times the transport weight of the device.
- Secure the device to prevent it tipping over and falling down during transport.
- Never transport the device sideways or upside down.

Storage conditions

- The device must be stored in the original packaging.
- Only store the device in dry rooms.
- The storage temperature must be between -20 °C and +60 °C.
- Humidity must not be condensing. Humidity must be between 10% and 80%.

4.2 Fastening the transport lock

Personnel:

- Trained user

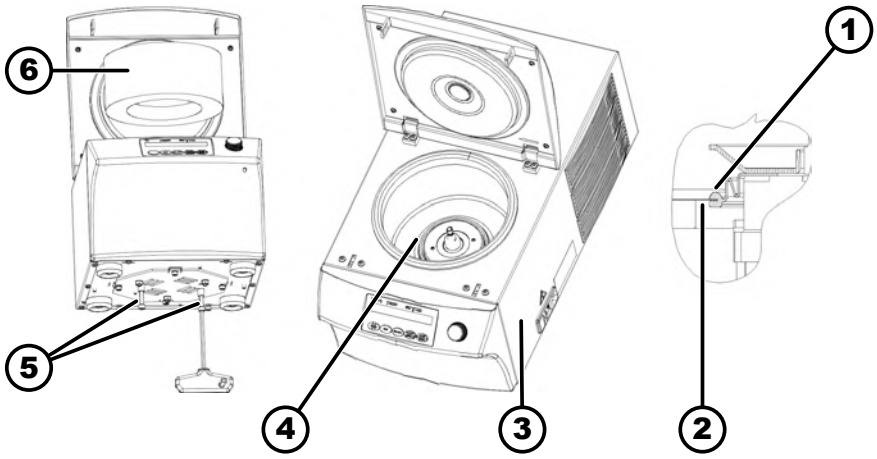


Fig. 13: Transport lock

1 Bellows
2 Edge of the centrifuging chamber
3 Right side of device
4 Motor cover
5 Screws and spacer sleeves
6 Foam cylinder

1. Open the lid.
2. For MIKRO 200 R:

   Check the bellows (*1*) under the motor cover (*4*) for correct seating: The edge of the centrifuging chamber (*2*) must be in the groove of the bellows.
3. Insert the foam cylinder (*6*).
4. Close the lid.
5. Lay the device down onto its right-hand side (*3*).
6. Screw in 2 screws with 2 spacer sleeves (*5*).

5 Commissioning

5.1 Unpacking the centrifuge

CAUTION

Danger of crushing due to parts falling out of the transport packaging.

- Keep the device balanced during the unpacking process.
- Only open the packaging at the points provided for this purpose.

CAUTION

Risk of injury from lifting heavy loads.

- Provide an adequate number of helpers.
- Note the weight. See ➦ *Chapter 3.1 'Technical data' on page 9*.

NOTICE

Damage to the device due to improper lifting.

- Do not lift the centrifuge by the control panel or the control panel holder.

Personnel:

- Trained user

1. If present: Remove the packaging tapes.
2. Lift the box up and remove the padding.
3. Remove the accessories and store them safely.
4. Place the device on a stable and level surface.

5.2 Removing the transport lock

Personnel:

- Trained user

The lid is closed.

1. Lay the device down onto its right-hand side (*3*).

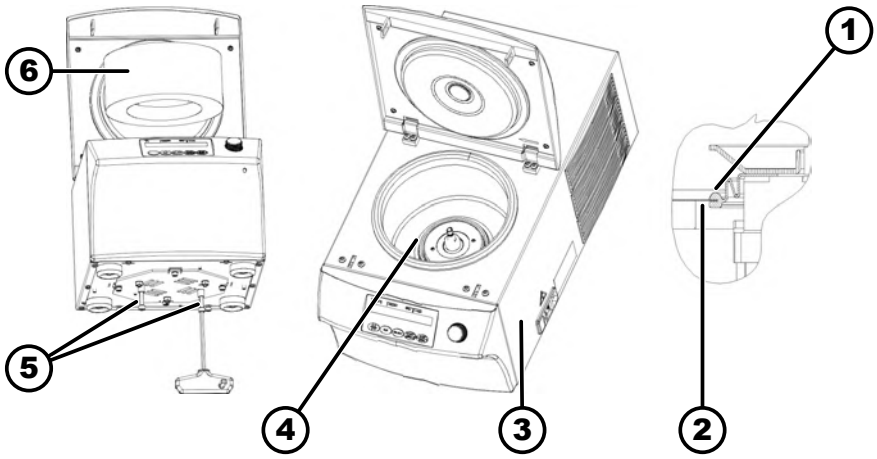


Fig. 14: Transport lock

1 Bellows
2 Edge of the centrifuging chamber
3 Right side of device
4 Motor cover
5 Screws and spacer sleeves
6 Foam cylinder

2. Remove 2 screws and 2 spacer sleeves (*5*).
3. Keep the screws and spacer sleeves in a safe place.
4. Open the lid.
5. Remove the foam cylinder (*6*).
6. Store the foam cylinder in a safe place.
7. For MIKRO 200 R:

   Check the bellows (*1*) under the motor cover (*4*) for correct seating: The edge of the centrifuging chamber (*2*) must be in the groove of the bellows.

5.3 Setting up and connecting the centrifuge

Setting up the centrifuge

WARNING

Risk of injury

Due to insufficient clearance from the centrifuge.

- As per EN / IEC 61010-2-020, no persons, hazardous materials or objects may be present within a safety zone of 300 mm around the centrifuge during a centrifugation run.
- Maintain a distance of 300 mm from the ventilation slots and ventilation openings of the centrifuge.
- The centrifuge's ventilation openings must never be blocked.

CAUTION

Risk of crushing and damage

Changes in position caused by vibration may cause the device to fall.

- Place the device on a stable and level surface.
- Select an installation area that is capable of bearing the weight of the device.
- Observe national and local regulations on safety and accident prevention.

NOTICE

Damage

Any deviation from the external temperature conditions will result in damage to the samples and device.

- Comply with the maximum and minimum permissible ambient temperatures.
- Avoid placing the device next to heat sources.
- Do not place the device in direct sunlight.
- Protect the device from frost.
- Maintain the required clearance around the device.

Personnel:

- Trained user

1. Place the device on a stable and level surface.
2. Maintain a distance of 300 mm around the device.
3. Comply with the ambient conditions in the technical data (➥ *Chapter 3.1 'Technical data' on page 9*).

Connecting the centrifuge

NOTICE

Damage

Property damage caused by unauthorised personnel.

- Do not allow persons without the appropriate authorisation to perform any work on or make changes to devices.
- Only authorised personnel may carry out maintenance and repairs.
- Obtain the manufacturer's approval or guidance before carrying out any work on the device.

NOTICE

Danger due to condensation in the event of temperature differences

Moisture may damage electrical components.

- Ensure that all surfaces are dry prior to commissioning or maintenance.
- If the temperature changes, wait until the device or component has become acclimatised.
- Prevent moisture from penetrating into sensitive components.
- If moisture forms, switch off the device immediately and allow it to dry properly.

Personnel:

- Trained user

1. A type B residual current circuit breaker must be used if the device is additionally protected with a residual current circuit breaker in the building installation.

   When using a different type, the residual current circuit breaker may either not switch off the unit if there is a fault on the unit, or it may switch off the unit even though there is no fault on the unit.
2. Check whether the mains voltage and mains frequency match the specification on the rating plate.
3. Connect the device to a standard mains socket using the mains cable.

5.4 Switching the centrifuge on and off.

Switching the centrifuge on

Personnel:

- Trained user

→ Set the mains switch to *[I]*.

➡ The buttons flash, depending on the centrifuge type.

The following indicators appear one after the other, depending on the centrifuge type:

- the centrifuge model and program version
- When the lid is closed: For centrifuges with cooling, *'OPEN OEFFNEN'* indicator. The lid opens in centrifuges without cooling.
- When the lid is open: The last centrifugation data used.

Switching off the centrifuge

The rotor is stationary.

→ Set the mains switch to *[0]*.

6 Operation

6.1 Opening and closing the lid

Opening the lid

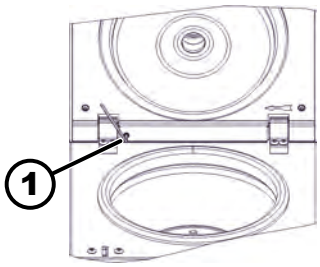


Fig. 15: Lid

1 Adjusting screw

Personnel:

- Trained user

The centrifuge is switched on.

The rotor is stationary.

→ Press the *[STOP/OPEN]* button.

➡ The lid unlocks by means of a motor.

Open the lid.

The lid opens automatically approx. 45°.

To change the opening angle, turn the adjusting screw (*1*) using the hex key supplied.

- Turning clockwise: Lid opens less.
- Turning anticlockwise: Lid opens more.

Closing the lid

CAUTION

Crushing hazard when closing the lid.

Danger of fingers getting crushed when the closing motor pulls the lid against the seal.

– No parts of the operator's body should be in the hazard zone of the lid when closing the lid.
– To close the lid, press on the lid from above.

NOTICE

Damage to the device caused by the lid slamming.

– Close the lid slowly.
– Do not slam the lid.

When the left side of the [STOP/OPEN] button flashes, press the [STOP/OPEN] button so that the motorised lid lock assumes the home position (open).

Personnel:

- Trained user

→ Close the lid and press the front edge of the lid down gently.

➡ The lid locks using a motor.

The left side of the *[STOP/OPEN]* button lights up.

6.2 Removing and installing the rotor

Removing the rotor

Personnel:

- Trained user

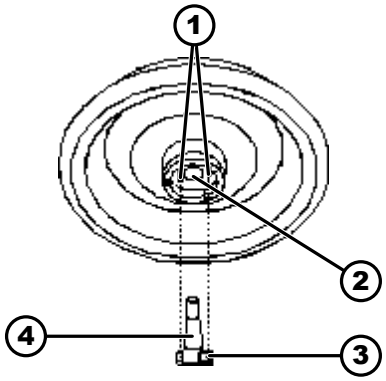


Fig. 16: Rotor installation and removal

1 Driver pins
2 Rotor hole
3 Driver
4 Motor shaft

1. Open the lid.
2. Loosen the rotor clamping nut using the supplied spanner.
   ➡ After passing the working point for lifting the rotor, the rotor detaches from the cone of the motor shaft (*4*).
3. Turn the clamping nut until the rotor can be lifted off the motor shaft.
4. Remove the rotor.

Installing the rotor

Personnel:

- Trained user

The lid is open.

1. Clean the motor shaft (*4*) and rotor hole (*2*).
2. Lightly grease the motor shaft (*4*), see ➥ *Chapter 8.2 'Instructions for cleaning and disinfection' on page 33*.
3. Place the rotor vertically on the motor shaft (*4*).

   The two driver pins (*1*) on the underside of the rotor must not rest on the driver (*3*) when screwing in the rotor.
4. Hand-tighten the rotor clamping nut using the supplied spanner.
5. Check that the rotor is firmly seated.

6.3 Loading

Filling centrifuge tubes

WARNING

Risk of injury from contaminated sample material.

Contaminated sample material escapes from the sample tube during centrifugation.

- Use centrifuge tubes with special screw caps for hazardous substances.
- For risk group 3 and 4 materials, use a biosafety system in addition to the sealable centrifuge tubes (see WHO's 'Laboratory Biosafety Manual').

NOTICE

Damage to the device due to highly corrosive substances.

Highly corrosive substances may impair the mechanical strength of rotors, buckets and accessories.

- Do not centrifuge highly corrosive substances.

Standard glass centrifuge tubes can be loaded up to RCF 4000 (DIN 58970 part 2).

Personnel:

- Trained user

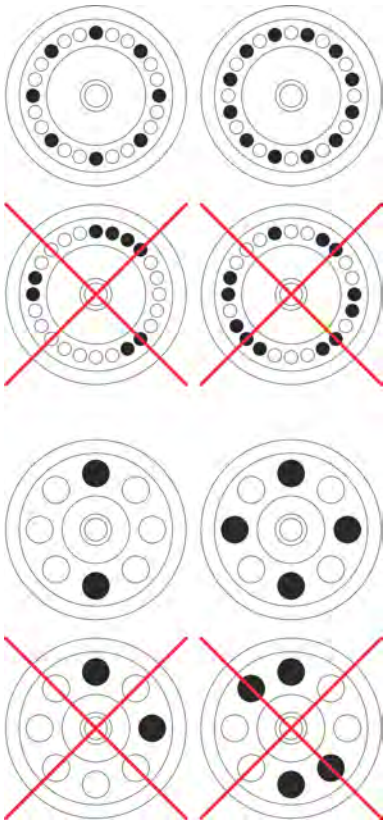
→ Fill centrifuge tubes outside the centrifuge.

The maximum capacity of the centrifuge tubes specified by the manufacturer must not be exceeded.

With angle rotors, the centrifuge tubes must only be filled to the extent that no liquid can be ejected from the tubes during the centrifugation run.

It must be ensured that there is a uniform fill level in the tubes in order to keep the weight differences in the centrifuge tubes as low as possible.

Loading the angle rotors



Personnel:

- Trained user

1. → Check that the rotor is firmly seated.
2. → The centrifuge tubes must be distributed evenly over all locations on the rotor.

No liquid must be allowed to enter the rotor and the centrifuging chamber when loading the rotor.

With rotors, the centrifuge tubes must only be filled to the extent that no liquid can be ejected from the tubes during the centrifugation run.

The weight of the permissible filling capacity is indicated on each rotor. The weight must not be exceeded.

6.4 Opening and closing the biosafety system

6.4.1 Explanation

The user must take appropriate actions when centrifuging hazardous substances or mixtures of substances that are toxic, radioactive or contaminated with pathogenic microorganisms.

Centrifuge tubes with special screw caps for hazardous substances must always be used.

For materials of risk group 3 and 4, a biosafety system must be used in addition to the sealable centrifuge tubes (see the World Health Organisation's "Laboratory Biosafety Manual").

In a biosafety system, a bioseal (sealing ring) prevents droplets and aerosols from escaping.

If the bucket of a biosafety system is used without the lid, the sealing ring must be removed from the bucket to prevent damage to the sealing ring during the centrifugation run.

Damaged biosafety systems are no longer microbiologically tight.

If no biosafety system is used, a centrifuge is not microbiologically tight in the sense of the EN / IEC 61010-2-020 standard.

Storage of biosafety systems

Biosafety systems must only be stored with the lid open to avoid damage to the sealing rings during storage.

6.4.2 Lid with screw cap without hole

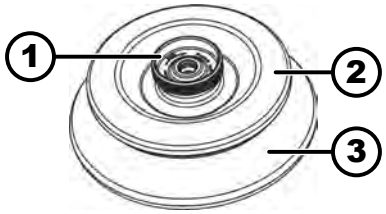


Fig. 17: Biosafety system

1 Rotary handle
2 Lid
3 Rotor

Closing

1. Place the lid (*2*) centrally on the rotor (*3*).
2. Turn the lid (*2*) at the rotary handle (*1*) clockwise until it is tightly closed.

Opening

1. Turn the lid (*2*) at the rotary handle (*1*) anticlockwise until it is open.
2. Remove the lid (*2*) from the rotor (*3*).

6.5 Centrifugation

6.5.1 Centrifugation in continuous operation

Personnel:

- Trained user

1. Set minutes and seconds at *'∞'* or retrieve a continuously running program.
2. Press the *[START/IMPULS]* button.
   ➡ The centrifugation run is started.

   The *[START/IMPULSE]* button lights up during the centrifugation run.

   The timing starts at *'00:00'*.

   The rotor speed or the RCF value, the temperature in the centrifuging chamber (only for centrifuges with cooling) and the elapsed time are displayed during the centrifugation run.

3. Press the *[STOP/OPEN]* button to cancel the centrifugation run.

   Ramp-down takes place with the set brake level. The brake level is displayed.

   An audible signal sounds when the rotor comes to a standstill.

   'OPEN OEFFNEN' is displayed.

6.5.2 Centrifugation with time preselection

Personnel:

- Trained user

1. Set centrifugation parameters or retrieve a program.
2. Press the *[START/IMPULS]* button.

   ➡ The centrifugation run is started.

   The *[START]* button lights up during the centrifugation run.

   The rotor speed or the RCF value, the temperature in the centrifuging chamber (only for centrifuges with cooling) and the remaining time are displayed during the centrifugation run.
3. Ramp-down takes place with the selected brake level after the time has elapsed or if the centrifugation run is cancelled.

   ➡ The brake level is displayed.

   An audible signal sounds when the rotor comes to a standstill.

   'OPEN OEFFNEN' is displayed.

   The right side of the *[STOP/OPEN]* button lights up when the centrifuge is in ramp-down.

   The left side of the *[STOP/OPEN]* button lights up when the rotor is at a standstill.

   The light on the *[START/IMPULS]* button and the right side of the *[STOP/OPEN]* button go out.

6.5.3 Short-term centrifugation

Personnel:

- Trained user

1. Press and hold the *[START/IMPULS]* button.

   ➡ The *[START/IMPULS]* button lights up during the centrifugation run.

   Timing starts at 00:00.

   The rotor speed or the RCF value, the temperature in the centrifuging chamber (only for centrifuges with cooling) and the elapsed time are displayed during the centrifugation run.
2. Release the *[START/IMPULSE]* button to end the centrifugation run.

   ➡ Ramp-down takes place with the set brake level. The brake level is displayed.

   An audible signal sounds when the rotor comes to a standstill.

   'OPEN OEFFNEN' is displayed.

6.6 Quick stop function

Personnel:

- Trained user

→ Press the *[STOP/OPEN]* button twice.

➡ Ramp-down with brake level "9" (shortest ramp-down time) is displayed and executed.

7 Software operation

7.1 Centrifugation parameters

7.1.1 Relative centrifugal force, RCF

The relative centrifugal force RCF is dependent on the speed and the centrifuging radius.

The relative centrifugal force RCF is stated as a multiple of the acceleration due to gravity (g).

The relative centrifugal force RCF is a dimensionless numerical value and is used to compare the separation and sedimentation performance.

$$\mathrm{RCF} = \left(\frac{\mathrm{RPM}}{1000}\right)^2 * \mathrm{r} * 1{,}118$$

$$\mathrm{RPM} = \sqrt{\frac{\mathrm{RCF}}{\mathrm{r} * 1{,}118}} * 1000$$

RCF = relative centrifugal force

RPM = Speed

r = centrifuging radius in mm = distance from the centre of the axis of rotation to the bottom of the centrifuge tube.

7.1.2 Centrifugation of substances or mixtures of substances with a density higher than 1.2 kg/dm³

The density of the substances or mixtures of substances must not exceed 1.2 kg/dm³ during centrifugation at maximum speed. The maximum permissible speed must be reduced for substances or substance mixtures with a higher density. The permissible speed can be calculated using the following formula:

$$\text{Reduced speed } (n_{red}) = \sqrt{\frac{1{,}2}{\text{Greater density [kg/dm}^3\text{]}}} * \text{maximum speed [RPM]}$$

For example: Maximum speed 4000 RPM, density 1.6 kg/dm³

$$n_{red} = \sqrt{\frac{1{,}2(\mathrm{kg/dm^3})}{1{,}6(\mathrm{kg/dm^3})}} * 4000\ \mathrm{RPM} = 3464\ \mathrm{RPM}$$

If, in exceptional cases, the maximum load indicated on the bucket is exceeded, the speed must also be reduced. The permissible speed can be calculated using the following formula:

$$\text{Reduced speed } (n_{red}) = \sqrt{\frac{\text{maximum load [g]}}{\text{actual load [g]}}} * \text{maximum speed [RPM]}$$

For example: Maximum speed 4000 RPM, maximum load 300 g, actual load 350 g

$$n_{red} = \sqrt{\frac{300\ \mathrm{g}}{350\ \mathrm{g}}} * 4000\ \mathrm{RPM} = 3703\ \mathrm{RPM}$$

Please contact the manufacturer if you are not sure.

7.2 Programming

7.2.1 Write protection for programs

The programs can be protected to prevent unintentional changes.

When the rotor is at a standstill, write protection can be enabled or disabled as follows:

1. Press and hold the *[SELECT]* button.
   ➡ *'SOUND/BELL'* is displayed after 8 seconds.
2. Press the *[SELECT]* button.
   ➡ *'LOCK'* is displayed.
3. Use *[Rotary knob]* to set *'OFF'* or *'ON'*.
   OFF = The programs are not write-protected
   ON = The programs are write-protected
4. Press the *[START/IMPULS]* button.
   ➡ The setting is stored.
   If ON is set: *'*** lock ***'* is displayed briefly.
   If OFF is set: *'*** ok ***'* is displayed briefly.

7.2.2 Opening or loading programs

1. Use the *[SELECT]* button to select the *'PROG RCL'* parameter.
2. Use the *[Rotary knob]* to set the desired program location.
3. Press the *[START/IMPULS]* button.
   ➡ *'*** ok ***'* is displayed briefly.
   The centrifugation data of the desired program location is displayed
4. To check the parameters: Press the *[SELECT]* button several times.
5. To exit the parameter indicator: Press the *[OPEN/STOP]* button or do not press any button for 8 seconds.

7.2.3 Entering or changing programs

1. Retrieve program.
2. If required: Press the *[RCF]* button to toggle between RPM and RCF indicator (*'> <'*).
3. If required: Press the *[SELECT]* button to select the desired parameter and set it with the *[Rotary knob]*.
   The parameters t/min and t/sec must be set to 0 using the *[Rotary knob]* to set continuous operation. Continuous operation is shown in the indicator with *'∞'*.
4. Use the *[SELECT]* button to select the *'PROG STO'* parameter.
5. Use the *[Rotary knob]* to set the desired program location.

6. Press the *[START/IMPULS]* button.
   ➡ Settings are stored in the desired program location.
   *'*** ok ***'* is displayed briefly.
   The settings are always stored in program location # if the *[START/IMPULS]* button is pressed without the *'PROG STO'* parameter being selected.

7.3 Cooling (for centrifuges with cooling)

7.3.1 Instructions, cooling

The temperature setpoint can be adjusted from -10 °C to +40 °C.

The lowest achievable temperature is rotor dependent.

7.3.2 Standby cooling

After a centrifugation run, standby cooling is delayed and the display shows *'Deckel entriegelt'*.

The delay time is adjustable from 1 to 5 minutes, in 1-minute increments. It is preset to 1 minute.

- The rotor is stationary.
- The lid is open

1. Press and hold the *[Cooling]* button.
   ➡ *'t/min = X '* is displayed after 8 seconds.
2. Use the *[Rotary knob]* to set the delay time.
3. Press the *[START/IMPULS]* button.
   ➡ The setting is stored.
   *'*** ok ***'* is displayed briefly.
4. Press the *[STOP/OPEN]* button twice or wait 8 seconds to exit the menu.

7.3.3 Precooling the rotor

Starting

The rotor is stationary.

1. Press the *[Cooling]* button.
2. Press the *[STOP/OPEN]* button.
   ➡ Precooling of the rotor is terminated.
   Ramp-down takes place with the selected brake level.
   The brake level is displayed.

Set

The precooling speed is adjustable from 500 RPM up to the maximum rotor speed in increments of 10 RPM. It is preset to 10000 RPM.

- The rotor is stationary.
- The lid is open.

1. Press and hold the *[Cooling]* button.
   ➡ *'t/min = X '* is displayed after 8 seconds.
2. Press the *[Cooling]* button.
   ➡ Precooling speed *'RPM = XXXX'* is displayed.
3. Use the *[Rotary knob]* to set the precooling speed.

4. Press the *[START/IMPULS]* button.
   ➡ The setting is stored.
   *'*** ok ***'* is displayed briefly.
5. Press the *[STOP/OPEN]* button twice or wait 8 seconds to exit the menu.

7.4 Machine Menu

7.4.1 Querying system information

Parameter query

The rotor is stationary.

1. Press and hold the *[SELECT]* button for 8 seconds.
   ➡ *'SOUND/BELL'* is displayed.
2. Press the *[SELECT]* button repeatedly until *'FU/CCI -S.'* is displayed.
   Program version for the frequency inverter
3. Press the *[SELECT]* button repeatedly until *'HOURS'* is displayed.
   Internal operating hours (the time during which the centrifuge was switched on)
4. Turn to the right with the *[Rotary knob]*.
   ➡ *'STARTS'* is displayed.
   Number of centrifugation runs
5. Turn to the right with the *[Rotary knob]*.
   ➡ *'ROTORCHG1'* is displayed.
   Internal operating hour of the last rotor change
6. Turn to the right with the *[Rotary knob]*.
   ➡ *'ROTORCHG2'* is displayed.
   Internal operating hour of the penultimate rotor change
7. Turn to the right with the *[Rotary knob]*.
   ➡ *'OPhoursCHG'* is displayed.
   Internal operating hour of the last operating hours change
8. Turn to the right with the *[Rotary knob]*.
   ➡ *'IMBALCHG'* is displayed.
   Internal operating hour of the last imbalance cut-off change
9. Turn to the right with the *[Rotary knob]*.
   ➡ *'OffsetCHG'* is displayed.
   Internal operating hour of the last offset adjustment
10. Press the *[STOP/OPEN]* button to exit the menu.

7.4.2 Querying operating hours

The rotor is stationary.

1. Press and hold the *[SELECT]* button.
   ➡ *'SOUND/BELL'* is displayed after 8 seconds.
2. Press the *[SELECT]* button repeatedly until *'CONTROL:'* is displayed.
   ➡ *'CONTROL:'* and the operating hours are displayed.
3. Press the *[STOP/OPEN]* button to exit the menu.

7.4.3 Audible signal

7.4.3.1 General

The audible signal sounds:

- after a problem occurs in the 2 s interval.
- after completion of the centrifugation run and rotor standstill in the 30 s interval.

Opening the lid or pressing any button stops the audible signal.

7.4.3.2 Setting an audible signal

1. Press and hold the *[SELECT]* button.
   ➡ *'SOUND / BELL ON'* or *'SOUND / BELL OFF'* is displayed after 8 seconds.
2. Use *[Rotary knob]* to set *'OFF'* or *'ON'*.
   OFF = audible signal disabled
   ON = audible signal enabled
3. Press the *[START/IMPULS]* button.
   ➡ The setting is stored.
   *'*** ok ***'* is displayed briefly.

8 Cleaning and care

8.1 Overview table

Chap.	Task to execute	if required	daily	weekly	Annually	Page
8	**Cleaning and care**					32
8.3	**Cleaning**					33
8.3	Cleaning the device		X			33
8.3	Cleaning biosafety systems			X		34
8.3	Cleaning accessories			X		34
8.4	**Disinfection**					34
8.4	Disinfecting the device	X				34
8.4	Disinfecting the accessories	X				34
8.5	**Maintenance**					35
8.5	Greasing the rubber seal of the centrifuging chamber			X		35
8.5	Greasing the rubber seal of the biosafety system			X		35
8.5	Checking the accessories			X		35

Chap.	Task to execute	if required	daily	weekly	Annually	Page
8.5	Checking the biosafety system			X		35
8.5	Centrifuging chamber damage inspection				X	35
8.5	Greasing the motor shaft				X	35
8.5	Accessories with a limited service life	X				35
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8.2 Instructions for cleaning and disinfection

DANGER

Risk of contamination

Inadequate cleaning or failure to observe the cleaning instructions can lead to contamination risks.

- Observe national and local regulations on safety and accident prevention.
- Observe cleaning instructions.
- Wear personal protective equipment when cleaning the device.
- Comply with laboratory regulations (e.g. TRBAs, the German Protection against Infection Act, hygiene plan) for handling biological agents.

- The device and its accessories must not be cleaned in dishwashers.
- Only perform hand cleaning and liquid disinfection.
- The water temperature must not exceed 25 °C.
- To prevent any corrosion due to use of detergents or disinfectants, it is essential to follow the special application instructions provided by the manufacturers of the detergent or disinfectant.

Disinfectant:

- Surface disinfectant (not disinfectant for hands or instruments)
- Ethanol as the sole active substance.
  Do not use an ethanol-propanol mixture to disinfect the viewing window in the lid of the device.
- Concentration is not less than 30 %
- pH: 6 – 8
- Non-corrosive

8.3 Cleaning

Cleaning the device

1. Open the lid.
2. Switch off the device and disconnect it from the power supply.
3. Remove accessories.
4. Clean the centrifuge housing and the centrifuging chamber with soap or a mild detergent and a damp cloth.

5. Remove any detergent residues with a damp cloth after using detergents.
6. The surfaces must be dried immediately after cleaning.
7. Dry the centrifuging chamber with an absorbent cloth if condensation forms.

Cleaning biosafety systems

1. Clean the biosafety system using the detergent and a damp cloth.
2. Remove any detergent residues with a damp cloth after using detergents.
3. Dry the accessories immediately after cleaning using a lint-free cloth and oil-free compressed air. Dry all cavities completely using oil-free compressed air.

Cleaning accessories

1. Clean the accessories using the detergent and a damp cloth.
2. Remove any detergent residues with a damp cloth after using detergents.
3. Dry the accessories immediately after cleaning using a lint-free cloth and oil-free compressed air. Dry all cavities completely using oil-free compressed air.

8.4 Disinfection

Disinfection must always be preceded by cleaning of the components concerned.

See ➦ Chapter 8.3 'Cleaning' on page 33

Disinfectant concentration and application time according to the manufacturer's instructions.

Disinfecting the device

CAUTION

Risk of injury due to ingress of water or other liquids.

- Protect the device against external liquids.
- Do not disinfect the device using spray.

1. Open the lid.
2. Switch off the device and disconnect it from the power supply.
3. Remove accessories.
4. Clean the housing and centrifuging chamber using disinfectant.
5. Remove any disinfectant residues with a damp cloth after using disinfectants.
6. The surfaces must be dried immediately after cleaning.

Disinfecting the accessories

1. Disinfect the accessories using the disinfectant.
2. Wet all cavities with bubble-free disinfectant.
3. Remove the disinfectant residues or leave them to dry after using disinfectants.

Autoclaving

The following accessories may be autoclaved at 121 °C / 250 °F (20 min):

- Swing-out rotors
- Aluminium angle rotors
- Metal buckets
- Lid with bioseal
- Inserting

No statement can be made about the resulting degree of sterility.

The lids of the rotors and bucket must be removed before autoclaving.

Autoclaving accelerates the ageing of materials. It may cause changes in colour. After autoclaving, the rotors and accessories are to be visually inspected for damage and any damaged parts are to be replaced immediately.

The sealing ring in question is to be replaced if there are signs of cracking, embrittlement or wear. For lids with non-replaceable sealing rings, the whole lid must be replaced.

The sealing rings must be replaced after autoclaving to ensure the tightness of the biosafety systems.

8.5 Maintenance

Greasing the rubber seal of the centrifuging chamber

→ Rub the sealing ring lightly with a rubber care product.

Greasing the rubber seal of the biosafety system

→ Rub the sealing ring lightly with a rubber care product.

Checking the accessories

1. → The accessories shall be checked for wear and corrosion damage.
2. → Check that the rotor is firmly seated.

Checking the biosafety system

1. → Visually check all parts of the biosafety system for damage.
2. → Check the correct installation position of the sealing ring(s) of the biosafety system.
3. → Replace the damaged parts of the biosafety system.
4. → Replace the sealing ring in question immediately if there are signs of cracking, embrittlement or wear. For lids with non-replaceable sealing rings, the whole lid must be replaced.

Centrifuging chamber damage inspection

→ Check the centrifuging chamber for damage.

Greasing the motor shaft

1. → Remove accessories.
2. → Clean the motor shaft.
3. → Remove any detergent residues with a damp cloth after using detergents.
4. → Grease the motor shaft with Hettich Tubenfett 4051.
5. → Excess grease in the centrifuging chamber must be removed.

Accessories with a limited service life

The use of certain accessories is time-limited. For safety reasons, the accessories must no longer be used when either the maximum number of permissible run cycles marked on them or the expiry date marked on them has been reached.

- The maximum permissible number of run cycles or the expiry date can be seen on the accessories.
- The centrifuge is equipped with a cycle counter.

Replacing centrifuge tubes

CAUTION

Risk of injury from broken glass.

Broken glass may cause glass splinters and contaminated liquids to be found inside the centrifuge.

- Wear cut-resistant gloves.
- Wear protective goggles and a face mask.

Broken parts of the tube, glass splinters and spilled centrifuge material must be removed completely in the event of leakage or if a centrifuge tube breaks. Glass splinters that are not removed will cause further glass breakage.

The rubber inserts and the plastic sleeves of the rotors must be replaced after a glass breakage.

Disinfection must be carried out if the material is infectious.

9 Troubleshooting

9.1 Fault description

Customer service must be notified if the fault cannot be rectified based on the fault table. State the centrifuge type and serial number. Both numbers can be seen on the type plate of the centrifuge.

* Error number does not appear on the display.

Fault description	Cause	Remedy
no display	No power. Mains input fuses defective.	■ Check the supply voltage. ■ Check the mains input fuse. ■ The mains switch is in switch position *[I]*
TACHO - ERROR 1, 2	Tacho defective. Motor, electronics defective.	■ Open the lid. ■ Set the mains switch to *[0]*. ■ Wait at least 10 seconds. ■ Turn the rotor vigorously by hand. ■ Set the mains switch to *[I]*. The rotor must rotate while switching on.
IMBALANCE 3*	The rotor is unevenly loaded.	■ Open the lid. ■ Check the loading of the rotor. ■ Repeat the centrifugation run.
CONTROL - ERROR 4, 6	Lid lock error.	■ Perform a MAINS RESET.
CONTROL - ERROR 8	Lid lock error	■ Open the lid. ■ Set the mains switch to *[0]*. ■ Wait at least 10 seconds. ■ Turn the rotor vigorously by hand. ■ Set the mains switch to *[I]*. The rotor must rotate while switching on.

Fault description	Cause	Remedy
N > MAX 5	Overspeed.	■ Perform a MAINS RESET.
N < MIN 13	Underspeed.	■ Perform a MAINS RESET.
MAINS INTERRUPT 11*	Loss of mains power during the centrifugation run. The centrifugation run was not completed.	■ Open the lid. ■ Press the *[START/IMPULS]* button. ■ If required: Repeat the centrifugation run.
CONTROL-ERROR 21, 22, 25, 27, 29	Error/defect in electronics.	■ Perform a MAINS RESET.
CONTROL-ERROR 23	Error/defect in control panel.	■ Perform a MAINS RESET.
SER I/O-ERROR 30, 31, 33, 36	Error/defect in electronics.	■ Perform a MAINS RESET.
°C * -ERROR 51-53, 55	Error/defect in electronics.	■ Perform a MAINS RESET.
FU/CCI-ERROR 60-64, 67, 68, 82-86	Error/defect in electronics/ motor.	■ Perform a MAINS RESET.
SYNC-ERROR 90	Error/defect in electronics.	■ Perform a MAINS RESET.
SENSOR-ERROR 91, 92	Error/defect in imbalance sensor.	■ Perform a MAINS RESET.
KEYBOARD-ERROR	Error/defect in control panel.	■ Perform a MAINS RESET.
 The left half of the display lights up.	-	■ Notify customer service.

9.2 Performing a MAINS RESET

1. Set the mains switch to *[0]*.
2. Wait 10 seconds.
3. Set the mains switch to *[I]*.

9.3 Emergency release

The lid cannot be unlocked by the motor in the event of a power failure. Emergency unlocking by hand must be performed.

WARNING

Risk of electric shock due to maintenance and servicing work on live device.

– Disconnect the device from the mains before carrying out repairs and maintenance.

WARNING

Danger of cutting and crushing due to moving rotor.

– Do not open the lid until the rotor has stopped.

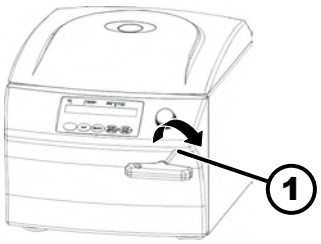

Fig. 18: Emergency release

1 Hole

Personnel:

- Trained user

1. Look through the window in the lid to ensure that the rotor is stationary.
2. Insert the hex key horizontally into the hole (*1*) and turn clockwise until the lid opens.
3. Remove the hex key from the hole (*1*).
4. Check whether the left side of the *[STOP/OPEN]* button flashes when power is restored.

   When the left side of the *[STOP/OPEN]* button flashes, press the *[STOP/OPEN]* button so that the motorised lid lock assumes the home position (open) again.

9.4 Replacing the mains input fuse

WARNING

Risk of electric shock due to maintenance and servicing work on live device.

– Disconnect the device from the mains before carrying out repairs and maintenance.

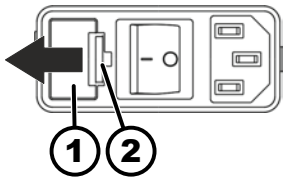

Fig. 19: Mains input fuse

1 Fuse holder
2 Snap lock

Personnel:

- Trained user

The mains fuses are located next to the mains switch.

The mains switch is in switch position *[O]*

1. Disconnect the mains cable from the device plug.
2. Press the snap lock (*2*) against the fuse holder (*1*) and pull it out.
3. Replace the defective mains input fuses.

   Only use fuses with the nominal value specified for the type: see the table below.
4. Push in the fuse holder (*1*) until the snap lock engages.
5. Reconnect the device to the mains.

Model	Type	Fuse	Order no.
MIKRO 200	2400	T 3.15 AH/250 V	E997
MIKRO 200	2400-01	T 5 AH/250 V	E914
MIKRO 200 R	2405, 2405-07	T 5 AH/250 V	E914
MIKRO 200 R	2405-01	T 8 AH/250 V	E738

10 Disposal

10.1 General instructions

The device can be disposed of via the manufacturer.

A Return Material Authorisation (RMA) form must always be requested for a return.

If necessary, contact the Technical Service Department of the manufacturer:

- *Andreas Hettich GmbH*
- *Föhrenstraße 12*
- *78532 Tuttlingen, Germany*
- *Phone: +49 7461 705 1400*
- *E-Mail: service@hettichlab.com*

WARNING

Risk of soiling and contamination

Damage to the environment and health due to improper disposal.

- Observe national and local environmental protection and disposal regulations to ensure proper disposal or recycling. Separate metals, non-metals, composite materials and auxiliary materials by type and dispose of them in an eco-friendly manner.
- The device may only be disassembled and disposed of by trained and authorised service technicians.

The device is intended for the commercial sector ("Business to Business" - B2B).

According to Directive 2012/19/EU, the devices may no longer be disposed of with household waste.

The devices are assigned to the following groups according to the Stiftung Elektro-Altgeräte Register (EAR (German foundation under civil law)):

- Group 1 (heat exchangers)
- Group 5 (small devices)

The crossed-out wheelie bin symbol indicates that the device must not be disposed of with household waste. Regulations governing disposal of such devices may differ in individual countries. If necessary, contact the supplier.

Fig. 20: Household waste ban

11 Index

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Andreas Hettich GmbH
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 **2025-06-13** until **2027-05-25**.

Fred Wenke
Head of Certification Body
Munich, 2025-06-16

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

ENCLOSURE OF CERTIFICATE

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

certificate holder:

Andreas Hettich GmbH
Föhrenstr. 12
78532 Tuttlingen
Germany

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

Fred Wenke
Head of Certification Body
Munich, 2025-06-16

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

CERTIFICATE

This is to certify that the company

Andreas Hettich GmbH

Föhrenstraße 12
78532 Tuttlingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	546262 MDSAP16
Certificate unique ID	1000215089
Effective date	2025-06-10
Expiry date	2028-06-09
Frankfurt am Main	2025-05-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to certificate
Certificate registration No.: 546262 MDSAP16
Certificate unique ID: 1000215089
Effective date: 2025-06-10

Andreas Hettich GmbH

Föhrenstraße 12
78532 Tuttlingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
100119401 **Andreas Hettich GmbH & Co.KG** Föhrenstraße 25 78532 Tuttlingen Germany	Manufacturing of parts and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes. -AUS (a), BRA, CND, JPN, USA (a,b,c,d) REPs FEI No.: F002477
100119406 **Andreas Hettich GmbH & Co.KG** Föhrenstraße 12 78532 Tuttlingen Germany	Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F002477**

Annex to certificate
Certificate registration No.: 546262 MDSAP16
Certificate unique ID: 1000215089
Effective date: 2025-06-10

Andreas Hettich GmbH

Föhrenstraße 12
78532 Tuttlingen
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821

Déclaration de conformité UE
EU Declaration of conformity

du fabricant | of the manufacturer

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

Par la présente, nous déclarons sous notre responsabilité, sans participation d'un organisme notifié, que le dispositif désigné:

Type de dispositif	**Microcentrifugeuse**
Nom	**MIKRO 200** **MIKRO 200 R**
UDI-DI de base	**040506740100109K**
GMDN	**17452**
Classification	**Dispositif de diagnostic in vitro, classe A (annexe VIII, règle 5)**
Conformément au	**règlement (UE) 2017/746 annexe IX**

avec les accessoires évalués comme conformes au dispositif d'après la liste d'accessoires de la documentation technique correspondante, satisfait aux dispositions pertinentes du règlement (UE) 2017/746 relatif aux dispositifs de diagnostic in vitro.

utilisation conforme aux dispositions

La centrifugeuse **MIKRO 200 / MIKRO 200 R** est un dispositif de diagnostic in vitro conformément au règlement relatif aux dispositifs de diagnostic in vitro (UE) 2017/746.

Le dispositif sert à centrifuger ainsi qu'à enrichir des échantillons d'origine humaine pour un traitement ultérieur à des fins de diagnostic. L'utilisateur peut régler les paramètres physiques modifiables concernés dans les limites définies par le dispositif.

La centrifugeuse peut être utilisée uniquement par un personnel qualifié dans des laboratoires fermés. La centrifugeuse est destinée uniquement à la fonction citée ci-dessus. L'utilisation conforme aux dispositions comprend le respect de toutes les indications énoncées dans le mode d'emploi et le respect des consignes d'inspection et de maintenance.

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

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**

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.

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.

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.

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.

Toute utilisation différente ou dépassant ce cadre est considérée comme non conforme. La société Andreas Hettich GmbH n'est pas responsable des dommages qui en résultent.

Le dispositif satisfait également aux dispositions applicables des directives et règlements européens suivants

- 2006/42/CE « Directive relative aux machines »
- 2014/30/UE « Directive CEM »
- 2014/35/UE « Directive basse tension »
- 2011/65/UE « Directive RoHS »
  (sans intervention d'un organisme notifié)
- (CE) 1907/2006 « Règlement REACH »
  (sans intervention d'un organisme notifié)

Normes appliquées :
voir la liste des normes appliquées qui fait partie de la documentation technique.

Any other use or use beyond this is considered improper. Andreas Hettich GmbH 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, 25.11.2024

Klaus-Günter Eberle
Gérant, Chief Executive Officer

CE

La présente déclaration de conformité est valable du 25/11/2024 au 24/10/2025	This declaration of conformity is valid from 25.11.2024 until 24.10.2025

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Andreas Hettich GmbH
Föhrenstraße 12
78532 Tuttlingen
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Design, development, manufacture, distribution, and maintenance of laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for separating blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2025-10-25	Registration No.	D1459300008
Valid until	2028-10-24	Report No.	P25-00101-322726

Stuttgart, 2025-08-01

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

Sites included in the certification:

Location	Scope
Andreas Hettich GmbH Föhrenstraße 12 78532 Tuttlingen Germany	Design, development, manufacture, distribution, and maintenance of laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for separating blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes
Andreas Hettich GmbH Föhrenstraße 25 78532 Tuttlingen Germany	Maintenance and manufacture of parts for laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for the separation of blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes

Stuttgart, 2025-08-01

Certification Body