Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 161007**

Certificate Holder: **Memmert GmbH + Co. KG**
Äußere Rittersbacher Str. 38
91126 Schwabach
Germany

including the locations according to annex

Scope: Design and development, production, distribution and service of electrical laboratory equipment, sterilizers, ovens, incubators, warming and cooling incubators, clime testing ovens, vacuum ovens, CO2 incubators, humidity chambers and water-/oil baths

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-09-25 until 2027-09-24.
First certification 2018

2024-09-24

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Digitally signed by Bolea Petru
Date: 2026.07.20 16:57:14 EEST
Reason: MoldSign Signature
Location: Moldova
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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 161007**

No.	Location	Scope
/01	c/o Memmert GmbH + Co. KG Äußere Rittersbacher Str. 38 91126 Schwabach Germany	Production and distribution of electrical laboratory equipment, sterilizers, ovens, incubators, warming and cooling incubators, clime testing ovens, vacuum ovens, CO2 incubators, humidity chambers and water-/oil baths
/02	c/o Memmert GmbH + Co. KG Willi-Memmert-Str. 90-96 91186 Büchenbach Germany	Design and development, production, distribution and service of electrical laboratory equipment, sterilizers, ovens, incubators, warming and cooling incubators, clime testing ovens, vacuum ovens, CO2 incubators, humidity chambers and water-/oil baths

2024-09-24

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147353 0001

Report No.: 21231982 015

Manufacturer:
Memmert GmbH + Co. KG
Äußere Rittersbacher Str. 38
91126 Schwabach
Deutschland

Products:
Dry Heat Sterilizers and CO2 Incubators
(see attachment for products and sites included)

Replaces Certificate, Registration No.: HD 60106200 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-27

Date: 2020-02-27

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147353 0001
Report No.: 21231982 015

Manufacturer:
Memmert GmbH + Co. KG
Äußere Rittersbacher Str. 38
91126 Schwabach
Deutschland

Products included:

Sterilizing Units Dry Heat, Type series S

CO2 Incubators
- ICO50med
- ICO105med
- ICO150med
- ICO240med

Site included:
- Memmert GmbH + Co. KG
  Willi-Memmert-Str. 90-96
  91186 Büchenbach, Germany

Activities: Production

Notified Body

Date: 2020-02-27

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Manufacturer‘s Declaration

The Manufacturer’s Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificate) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Memmert GmbH + Co. KG	
Manufacturer address and contact details	Äussere Rittersbacherstraße 38 D-91126 Schwabach Deutschland	
Single Registration Number (SRN) (if available)	DE-MF-000012127	
Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH	• See attached schedule
Notified body number (if applicable)	0197	• See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 60147353 0001	• See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024	• See attached schedule
End date of extended validity / transition period	31.12.2028	• See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed devices in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Manufacturer‘s Declaration

Directive Certificate as listed above or in the attached schedule 2023

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - Expired/expires after 20 March 2023:

    Formal application(s) to the notified body in accordance with Section 4.3, first subpara-graph of Annex VII MDR for conformity assessment has been made or will be submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System

- A QMS in accordance with Article 10(9) MDR is in place.

Device(s) as listed in the attached schedule

- The devices continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or ot her persons, or to other aspects of the protection of public health

Memmert GmbH + Co. KG
Schwabach, 19.02.2024
Signed for and on behalf of the manufacturer:

Dr. Jan Wittstatt, PRRC
jwittstatt@memmert.com

Manufacturer‘s Declaration

Schedule of Devices

The above Manufacturer’s Declaration is valid for the following devices:

Identification of the devices	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Sterilizing Units Dry Heat, Type series S	HD 60147353 0001	26.05.2024	TÜV Rheinland LGA Products GmbH - 0197	TÜV Rheinland LGA Products GmbH - 0197	31.12.2028
CO2 Incubators - ICO50med - ICO105med - ICO150med - ICO240med	HD 60147353 0001	26.05.2024	TÜV Rheinland LGA Products GmbH - 0197	TÜV Rheinland LGA Products GmbH - 0197	31.12.2028

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EC Declaration of Conformity

Manufacturer´s name and address:	Memmert GmbH + Co. KG Äussere Rittersbacherstraße 38 D-91126 Schwabach Germany
Product:	CO2 Incubators
Type:	ICO…/50/105/150/240
Nominal voltage:	AC 230 V 50/60 Hz, alternative AC 115 V 50/60 Hz

The designated product is in conformity with the European Low Voltage Directive

2014/35/EU

including amendments

Council Directive on the approximation of the laws of the Member States relating to Electrical equipment for use within certain voltage limits

Full compliance with the standards listed below proves the conformity of the designated product with the essential protection requirements of the above-mentioned EC Directive:

EN 61010-1:2010, EN 61010-1:2010/A1:2019/AC:2019-04, EN 61010-1:2010/A1:2019; EN IEC 61010-2-010:2020

The designated product is in conformity with the European EMC-Directive

2014/30/EU

including amendments

Council Directive of 03 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility

Full compliance with the standards listed below proves the conformity of the designated product with the essential protection requirements of the above-mentioned EC Directive:

EN 61326-1:2013

The object described in the declaration above corresponds to the directive 2011/65/EC of the European Parliament and the Council of 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Schwabach, 27.01.2023

Legally binding signature of the issuer:

Christiane Riefler-Karpa, managing director