

# 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:

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## 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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.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.

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## Quality Management System

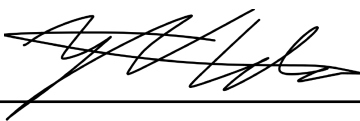
- A QMS in accordance with Article 10(9) MDR is in place.

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## 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 of 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:



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Dr. Jan Wittstatt, PRRC  
jwittstatt@memmert.com

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## 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