# 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<br>D-91126 Schwabach<br>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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.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.

## 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<br>- ICO50med<br>- ICO105med<br>- ICO150med<br>- ICO240med | HD 60147353 0001 | 26.05.2024 | TÜV Rheinland LGA Products GmbH - 0197 | TÜV Rheinland LGA Products GmbH - 0197 | 31.12.2028 |