

EC Declaration of Conformity

Manufacturer's name and address	Memmert GmbH + Co. KG Äussere Rittersbacherstraße 38 D-91126 Schwabach Germany
Type:	Incubators
Manufacturer's SRN:	DE-MF-000012127
Type:	INxxm, xx=30/55/75/110/160/260/450/750 INxxmX2, xx=30/55/75/110/160/260/450/750 IFxxm, xx=30/55/75/110/160/260/450/750 IFxxmX2, xx=30/55/75/110/160/260/450/750 Basic-UDI-DI: 42518175Im012GV
Nominal voltage:	AC 230 V 50/60 Hz, alternative AC 115 V 50/60 Hz
Intended use:	The appliance may be used for heating fango, silicate and APS packs for physical therapy and keeping them warm.

Class I, according to regulation (EU) 2017/745, Annex VIII Chapter III Rule 13

This product complies with the provisions of the regulation

(EU) 2017/745

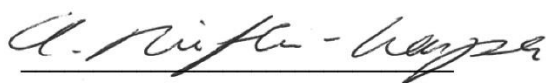
Including annex and amendments

on medical devices, amendment to Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The product described fulfils the requirements of Directive 2011/65/EC of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. The sole responsibility for issuing this declaration of conformity lies with the manufacturer.

Schwabach, 21.02.2024

Legally binding signature of the issuer:



Christiane Riefler-Karpa, managing director

Intended use as medical device

Memmert is bringing medical devices of class I according to EU Directive (EU) 2017/745 into circulation.

Type	Intended use as medical device	Classification according to (EU) 2017/745
UNmplus, UFmplus	The appliance may be used for heating fango, silicate and APS packs for physical therapy and keeping them warm.	I
UNm, UFm, INm, IFm	The appliance may be used for heating fango, silicate and APS packs for physical therapy and keeping them warm.	I
INmplus, IFmplus	Im may be used for heating fango, silicate and APS packs for physical therapy and keeping them warm. Implus may be used for temperature control of rinsing and infusion solutions and contrast agents.	I
IFbw	The appliance is used to heat non-sterile cloths and covers. Any other use is improper and may cause damage or danger.	I

Memmert is bringing medical devices of class IIa and IIb into circulation according to MDD 93/42/EEC until 31.12.2028 according to the transitional provisions (EU) 2023/607 by the (EU) 2017/745 article 120 (2).

Type	Intended use as medical device	Classification according to 93/42/EEG
SNplus, SFplus	The product is intended for the sterilisation of medical devices with dry heat at atmospheric pressure.	IIb
SN, SF	The product is intended for the sterilisation of medical devices with dry heat at atmospheric pressure.	IIb
ICOmed	The CO2 incubator ICOmed is used to generate and maintain constant ambient conditions for the in-vitro fertilisation (IVF) application field, especially for the incubation of oocytes, spermatozoa and zygotes in special culture dishes for IVF application as well as for gene expression and the biosynthesis of RNA and proteins.	IIa