



EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching, Germany
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Single Registration Number: DE-MF-000006269

Medical device

Product family: Sphygmomanometers
Product group: GAMMA

We hereby declare, under our sole responsibility, the conformity of the following products in accordance with MDD 93/42/EEC.

Product name	GAMMA G5	GAMMA G7	GAMMA GP
Basic UDI-DI	4053755_AS_01_45		
GMDN	16156		
UMDNS	16-156		
EMDN	C9006		
Classification	Class Im according annex IX		

CE₀₂₉₇

HEINE Optotechnik GmbH & Co. KG hereby declares that the products covered by this declaration are in conformity with this Regulation and, where applicable, with other relevant EU legislation providing for the issuing of an EU declaration of conformity.

References to any common specifications: None

Conformity assessment procedure chosen: MDD 93/42/EEC, annex VII in combination with annex V

This declaration of conformity is valid until a revised declaration of conformity is issued.

According to article 120 section 3 of the MDR (EU) 2017/745, a transition period for the sphygmomanometers is available. The sphygmomanometers could be placed on the market until 31 December 2028 under the directive 93/42/EEC (see annex on page 2 ff.).

Gilching, 15 January 2024
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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