EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching
Germany

Single Registration Number: Pending

HEINE Sphygmomanometers

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDD 93/42 EEC.

The aneroid Sphygmomanometers

Product name	Basic UDI-DI	GMDN	UMDNS
GAMMA G5	4053755_AS_01_45	16156	16-156
GAMMA G7			
GAMMA GP			
GAMMA XXL LF			

are class Im medical devices and meet all the applicable provisions set out in the directive 93/42/EEC according Annex VII in combination with Annex V.

CE 0297

This declaration of conformity is valid until a revised Declaration of Conformity is issued but not longer than January 27, 2024 (according Annex V EC-Certificate, registration no. 325735 MR5).

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 27 January 2024 under the directive 93/42/EWG.

Gilching, 26 May 2021
(Place and date of issue)

Thomas Sauerer / Director of Quality
(Name/function and signature)

HEINE OPTOTECHNIK
GmbH & Co. KG
Dornierstr. 6
82205 Gilching

EC-CERTIFICATE

(Production quality assurance)

This is to certify that the company

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has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sphygmomanometers and Accessories (Class Im)

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	325735 MR5
Certificate unique ID	170770401
Effective date	2020-07-31
Expiry date	2024-01-27
Frankfurt am Main	2020-07-31

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.