HEINE

HEINE Optotechnik GmbH & Co. KG · Dornierstr. 6 · 82205 Gilching · Germany
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DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstrasse 6
82205 Gilching/Germany

We declare, under sole responsibility, that the **Sphygmomanometers**

Group	Model	Type	GMDN	UMDNS
Aneroid Sphygmomanometers	GAMMA	G7	16156	16-156
		G5		
		GP		
		XXL LF		
Accessories	Cuff GAMMA G7/G5/GP	Infant, child, adult small, adult, adult large, thigh	34978	--
	Cuff GAMMA XXL LF	Infant, child, adult small, adult, adult large, thigh	34978	--

are class Im medical devices (their accessories are class I).

They 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).

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

Gilching, 31 August 2020
(Place and date of issue)

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

EC-CERTIFICATE

(Production quality assurance)

This is to certify that the company

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Germany

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

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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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.