EC-CERTIFICATE

(Production quality assurance)

This is to certify that the company

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
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,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

411.21 Version 1.0

CE-CERTIFICATO

(Garanzia di qualità della produzione)

Con la presente si certifica che la società

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
Germania

ha introdotto e applica un sistema di garanzia della qualità che si applica alla fabbricazione e l'ispezione finale dei prodotti.

Tramite una valutazione, documentata in un rapporto, eseguita da DQS Medizinprodukte GmbH e stato attestato che il sistema di garanzia della qualita corrisponde alle esigenze del

Allegato V della Direttiva 93/42/CEE del Consiglio concernente i dispositivi medici

in riferimento ai seguenti dispositivi medici:

Sfigmomanometri ed Accessori (Classe Im)

Il fabbricante è soggetto alla sorveglianza secondo al Allegato V, Punto 4. La marcatura CE con il numero di identificazione dell' organismo notificato (0297) può essere apposto sui prodotti elencati nel certificato. Il certificato è limitato nel caso di dispositivi di classe I(s) (I(s) = classe I prodotti immesi in commercio allo stato sterile) solo agli aspetti della fabbricazione che riguardano il raggiungimento e il mantenimento dello stato sterile. Il certificato è limitato nel caso di dispositivi di classe I(m) (I(m) = classe I prodotti con funzione di misura) solo agli aspetti di fabbricazione che riguardano la conformità dei prodotti ai requisiti metrologici.

Numero di registrazione del certificato	325735 MR5
Numero di identificazione unica	170770401
Data effettiva	2020-07-31
Data di scadenza	2024-01-27
Francoforte sul Meno	2020-07-31

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Direttrice generale

Dr. Thomas Feldmann
Capo della Autoritá di Certificazione

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH è un organismo notificato secondo la Direttiva 93/42/CEE del Consiglio concernente i dispositivi medici con il numero di identificazione 0297.

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
Germany

Date: 2023.12.21

Notified Body Confirmation Letter
Reference: 1000156810

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of 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

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
Germany

SRN: DE-MF-000006269

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

i.A. **Hovsep Aro**
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GAMMA G5 **Basic UDI-DI: 4053755_AS_01_45**	Class I devices with a measuring function	N/A	325735 MR5 (NB 0297)
GAMMA G7 **Basic UDI-DI: 4053755_AS_01_45**	Class I devices with a measuring function	N/A	325735 MR5 (NB 0297)
GAMMA GP **Basic UDI-DI: 4053755_AS_01_45**	Class I devices with a measuring function	N/A	325735 MR5 (NB 0297)
GAMMA XXL LF **Basic UDI-DI: 4053755_AS_02_48**	Class I devices with a measuring function	N/A	325735 MR5 (NB 0297)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-21	1000156810	Initial issue
	Cert-ID	description of change (e.g. addition of device XYZ to Table 1)
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)