EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

Medical device

Product family: **Sphygmomanometers**
Product group: GAMMA XXL

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

Product name	GAMMA XXL LF

Basic UDI-DI	4053755_AS_02_48
GMDN	16156
UMDNS	16-156
EMDN	C9006
Classification	Class Im according annex IX

CE 0297

HEINE Optotechnik GmbH & Co. KG hereby declares that the product covered by this declaration is 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.).

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

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

Thomas Sauerer / PRRC
(Name/function and signature)