

EU DECLARATION OF CONFORMITY

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

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Single Registration Number: DE-MF-000006269

STETHOSCOPES

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The stethoscopes

Product name	Basic UDI-DI	GMDN	UMDNS
GAMMA 3.1 Pulse Stethoscope	4053755_S_01_37	13755	13-750
GAMMA 3.2 Acoustic Stethoscope			
GAMMA 3.3 Acoustic Stethoscope			
GAMMA C3 Cardio Stethoscope			

are class I according to the risk classification of Annex VIII.

CE

References to any common specifications: N/A

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

Gilching, 20 January 2022

(Place and date of issue)

Thomas Sauerer / PRRC

(Name/function and signature)

HEINE OPTOTECHNIK GmbH & Co. KG

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