



ID-Nr. M-0002/01

EC-Declaration of Conformity for medical devices EG-Konformitätserklärung für Medizinprodukte

according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE GAMMA Stethoscope

UMDNS-Code: 13-750

in the following configurations

<u>Name or Type of device</u>	<u>Article-/Catalog-Number</u>
HEINE GAMMA 3.1® Pulse Stethoscope	M-000.09.941
HEINE GAMMA 3.2® Arcoustic Stethoscope	M-000.09.942
HEINE GAMMA 3.3® Arcoustic Stethoscope	M-000.09.943
HEINE GAMMA C3® Cardio Stethoscope	M-000.09.944

complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2011-11-15 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).

The applied harmonized standards are listed in the manufacturer's technical documentation.



Herrsching, 2011-11-15

Dipl.-Ing. (FH) Jörg Rönna
- Director Regulatory Affairs -

Oliver Heine, BA
- President and CEO -