HEINE GAMMA stethoscopes



HEINE Gamma 3.1 pulse stethoscope



HEINE GAMMA 3.2 acoustic stethoscope



HEINE GAMMA 3.3 paediatric stethoscope

DATA

Description	HEINE GAMMA 3.1 pulse stethoscope	HEINE GAMMA 3.2 acoustic stethoscope	HEINE GAMMA 3.3 paediatric stethoscope
Catalogue number	M-000.09.941	M-000.09.942	M-000.09.943
Document release date	July, 2024	July, 2024	July, 2024

MECHANICAL

Weight product	110g	120g	115g
Weight packaging (including product)	210g	220g	215g
Dimensions product	length: 705 mm, diameter chest piece: 48 mm	length: 705 mm, diameter chest piece: 48 mm	length: 705 mm, diameter chest piece: 34 mm
Dimensions packaging	280 x 100 x 37 mm	280 x 100 x 37 mm	280 x 100 x 37 mm
Imprints	membrane: HEINE logo, HEINE QUALITY - Made in Germany (2x), back: GAMMA 3.1	membrane: HEINE logo, HEINE QUALITY - Made in Germany (2x), back: GAMMA 3.2	membrane: HEINE logo, HEINE QUALITY - Made in Germany, back: GAMMA 3.3

GENERAL

Material	plastic, metal, silicone		
REACH RoHS	conform		
Phthalate	contains no phthalate		
Latex	contains no latex		
Biocompatibility	conform		
Surface	plastic, metal, silicone		
Environmental conditions for continuous operation	0 °C to +40 °C, 15% to 90 % rel. humidity, 620 hPa to 1060 hPa		
Environmental conditions for transport and storage	-40 °C to +70 °C, 15% to 90 % rel. humidity, 620 hPa to 1060 hPa		
Instructions for use*	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Suomi, Portugues		
Operating elements	Single chest piece with a high-quality membrane	Double chest piece with two different frequency ranges: a high-quality membrane for high frequencies on one side and an open bell for low frequencies on the other side	Double chest piece with two different frequency ranges: a high-quality membrane for high frequencies on one side and an open bell for low frequencies on the other side
Removable parts accessories	extra ear olives (small hard)		
Maintenance	change of membrane or ear olives		
Patents	N/A		

HYGIENIC REPROCESSING

Procedure	Please see detailed description for the reprocessing procedure online at www.heine.com
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CODES

Customs code (tariff number)	90189084
GTIN	4053755201068
Traceability	UDI code
Country of origin	Germany (DE)

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class I
Product classification (Canada)	class I
UMDNS code	13-750
GMDNS code	13755

FULFILLS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 13485	Medical devices - Quality management systems - requirements for regulatory purposes
(EU) 2017/745	On medical devices
ISO 14971	Medical devices - application of risk management to medical devices
IEC 62366-1	Medical devices - part 1: application of usability engineering to medical devices
ISO 17664	Processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals

^{*)} further languages on request

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