



DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
 Kientalstrasse 7
 D-82211 Herrsching/Germany

We declare, under sole responsibility, that the
 medical devices

Proctological Instruments


Group	Model	Type	GMDN	UMDNS
Instrument Head	Anoscope / Proctoscope Illumination Head	<blank>	--	--
	Instrument Head for HEINE UniSpec Tubes	<blank>		
Sigmoidoscope	F.O. Sigmoidoscopes with Distal Annular Illumination	<blank>	36635	15-058
Proctoscope	F.O. Proctoscopes with Distal Illumination	<blank>	35255	13-126
Anoscope	F.O. Anoscopes with Annular Illumination	<blank>	10156	10-156
Accessories	Tubes with straight direction of view	<blank>	--	--
	Tubes with 90° direction of view	<blank>		
	UniSpec Disposal Tubes	for Sigmoidoscope		
		for Proctoscope		
		for Anoscopes		
	Double Insufflation Bulb	<blank>	35800	16-448
	Hygiene Filter	<blank>	--	11-712
Sponge Holder	<blank>	35792	--	
Illumination Adaptor	<blank>	--	12-340	

which are class I
 meet all the applicable provisions set out in the directive 93/42/EEC,
 according **Annex VII.**



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

Herrsching, 21 January 2019
 (Place and date of issue)


 Thomas Sauerer / Director of Quality
 (Name/function and signature)

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