



## DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG  
 Dornierstrasse 6  
 82205 Gilching/Germany

We declare, under sole responsibility, that the **Proctological Instruments and their accessories**,

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

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.

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

Thomas Sauerer / Director of Quality

Gilching, 2 June 2020

(Place and date of issue)

(Name/function and signature)