



DECLARATION OF CONFORMITY

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

We declare, under sole responsibility, that the
 medical devices

Ophthalmic Instruments

Group	Model	Type	GMDN	UMDNS
Direct Ophthalmoscopes	BETA	200 LED	46786	12-817
		200		
		200 M2		
		200 S LED		
		200 S		
	K	180		
	mini3000	LED <blank>		
Option	Mounting Case	iC2	--	--
Ophthalmic Camera	iC2*	<blank>	--	--
Retinoscope	BETA	200 LED	32712	13-372
		200		
Hand-held Slitlamp	HSL	150	--	12-281
Retinometer	LAMBDA	100	--	14-382
Accessories	Loupe attachment for HSL	10x	--	--
	Ophthalmoscopy lenses A.R.	16D	--	--
		20D		
		30D		
Ophthalmic lamps	Focalux	<blank> mini3000	--	15-228
	Ophthalmic Examination Lamp	<blank>		
	Finoff Transilluminator	<blank>		
Indirect Ophthalmoscopes	OMEGA500	LED	46790	12-818
		<blank>		
	OMEGA200	<blank>		
	SIGMA250	M2 <blank>		
Option (OMEGA500)	DV1*	<blank>	--	--
Hand-held Indirect Ophthalmoscopes	Hand-held Indirect Ophthalmoscope	MONOCULAR	46788	12-818
		BINOCULAR	46790	

which are class I

meet all the applicable provisions set out in the directive 93/42/EEC,

according **Annex VII.**

(* according Directive 2014/35/EU)



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

Herrsching, 21 January 2019

(Place and date of issue)

A blue ink handwritten signature, appearing to read 'Thomas Sauerer', written over a horizontal line.

Thomas Sauerer / Director of Quality

(Name/function and signature)

HEINE OPTOTECHNIK

GmbH & Co. KG

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Germany