

**DECLARATION OF CONFORMITY**

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

We declare, under sole responsibility, that the medical devices:

**Ophthalmic Instruments**

Group	Model	Type	UMDNS
Direct Ophthalmoscopes	BETA	200	12-817
		200 M2	
		200 S	
	K	180	
	mini3000	LED <blank>	
Retinoscope	BETA	200	13-372
Hand-held Slitlamp	HSL	150	12-281
Retinometer	LAMBDA	100	14-382
Accessories	Loupe attachment for HSL	10x	
Ophthalmic lamps	Focalux	<blank>	15-228
		mini3000	
	Ophthalmic examination lamp	<blank>	
	Finoff Transilluminator	<blank>	
Indirect Ophthalmoscopes	OMEGA500	LED	12-818
		<blank>	
	OMEGA200	<blank>	
	SIGMA250	<blank>	
	SIGMA150	<blank>	
		M2	
		K	
	K/M3		
Video OMEGA 2C	<blank>		
Option (OMEGA500)	DV1*	<blank>	
Handheld Indirect Ophthalmoscopes	Handheld Indirect Ophthalmoscope	MONOCULAR	
		BINOCULAR	
Ophthalmoscopy lenses	A.R.	16D	
		20D	
		30D	

which are class I

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

according **Annex VII.**



(\*DV1: directive 2014/35/EU)



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

Herrsching, Mar. 17<sup>th</sup>, 2015

(Place and date of issue)

  
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**Bettina Seim**  
Head of Regulatory Affairs

(Name, function and signature)