



## EU DECLARATION OF CONFORMITY

**HEINE Optotechnik GmbH & Co. KG**  
Dornierstr. 6, 82205 Gilching  
Germany

Single Registration Number: DE-MF-000006269

### HEINE Indirect Ophthalmoscopes

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The indirect ophthalmoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
OMEGA 600	4053755_IO_01_5Z	46790	12-818
OMEGA 600 wired			
OMEGA 500 LED			
OMEGA 500			
SIGMA 250			
SIGMA 250 M2			
Indirect Ophthalmoscope MONOCULAR	4053755_HHIO_01_Q9	46788	12-818
Indirect Ophthalmoscope BINOCULAR		46790	

and

Product name	Basic UDI-DI	GMDN	UMDNS
mPack	4053755_PP_01_97		
mPack UNPLUGGED			
mPack mini			
BETA battery handle	4053755_BH_01_YN	--	16-337
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79		
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			


The indirect ophthalmoscopes are class I according to the risk classification of Annex VIII.



References to any common specifications: N/A

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

Gilching, 10 June 2021  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)

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