



## EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

### OTOSCOPES

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 otoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
BETA 200 LED	4053755_O_01_ZQ	12849	12-849
BETA 200			
BETA 400 LED			
BETA 400			
K180			
mini3000			
mini3000 F.O. LED			
mini3000 F.O.			
G100 LED			
G100			

and

mini3000 battery handle	4053755_BH_01_YN	--	16-337
BETA battery handle			
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			
mini3000 rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			

The otoscopes 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.

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

Gilching, 20 January 2022  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)



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### DIRECT 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 direct ophthalmoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
BETA 200 LED	4053755_DO_01_3Y	46786	12-817
BETA 200			
BETA 200 M2			
BETA 200 S LED			
BETA 200 S			
K180			
mini3000			
mini3000 LED			

and

mini3000 battery handle	4053755_BH_01_YN	--	16-337
BETA battery handle			
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			
mini3000 rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			

The direct 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.

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Gilching, 20 January 2022  
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Thomas Sauerer / PRRC  
(Name/function and signature)