



# EU DECLARATION OF CONFORMITY

**HEINE Optotechnik GmbH & Co. KG**  
**Dornierstr. 6, 82205 Gilching, Germany**  
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Single Registration Number: DE-MF-000006269

Medical device

**Product family:    Otoscopes**  
**Product group:    BETA**

We hereby declare, under our sole responsibility, the conformity of the following products in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

The otoscopes

<b>Product name</b>	BETA 200 LED	BETA 400 LED
<b>Basic UDI-DI</b>	4053755_O_01_ZQ	
<b>GMDN</b>	12849	
<b>UMDNS</b>	12-849	
<b>EMDN</b>	Z12149006	
<b>Classification</b>	Class I according annex VIII	

with the associated power sources as parts of the medical devices

<b>Battery handle</b>	BETA	BETA SLIM	Large
<b>Rechargeable handle</b>	BETA NT	BETA SLIM NT	BETA 4 USB
	BETA L	BETA 4SLIM NT	BETA 4 NT
<b>Wall unit</b>	EN 200	EN 200-1	

are medical devices of class I.





HEINE Optotechnik GmbH & Co. KG hereby declares that the products covered by this declaration are in conformity with this Regulation and, where applicable, with other relevant EU legislation providing for the issuing of an EU declaration of conformity.

References to any common specifications: None

Conformity assessment procedure chosen: Technical documentation according Annexes II and III

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

Gilching, 08 May 2024  
(Place and date of issue)

Timo Martin / CEO  
(Name/function and signature)

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