



## EU DECLARATION OF CONFORMITY

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

Single Registration Number: DE-MF-000006269

Medical device

**Product family: Indirect Ophthalmoscopes**  
**Product group: OMEGA 600**

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.

<b>Product name</b>	OMEGA 600	OMEGA 600 wired
<b>Basic UDI-DI</b>	4053755_IO_02_64	
<b>GMDN</b>	46790	
<b>UMDNS</b>	12-818	
<b>EMDN</b>	Z12120114	
<b>Classification</b>	Class I according annex VIII	




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, 22 August 2023  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)

**HEINE OPTOTECHNIK**  
**GmbH & Co. KG**  
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