



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 500

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 indirect ophthalmoscopes

Product name	OMEGA 500 LED	OMEGA 500
Basic UDI-DI	4053755_IO_02_64	
GMDN	46790	
UMDNS	12-818	
EMDN	Z12120114	
Classification	Class I according annex VIII	

with the associated power sources as part of the medical devices

Power pack	mPack	mPack UNPLUGGED
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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.

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

Gilching, 24 July 2023
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)