

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:

Headlights

Product group:

MicroLight/LoupeLight

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 headlights

Product name	MicroLight 2	LoupeLight 2	
Basic UDI-DI	1-DI 4053755 H 02 XE		
GMDN	46807		
UMDNS	11-963		
EMDN	Z129004		
Classification	Class I according annex VIII		

with the associated power source as part of the medical devices

Power pack	mPack mini
rower pack	IIII ack IIIIII

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, 22 August 2023 (Place and date of issue)

Thomas Sauerer / PRRC (Name/function and signature)