

## **EU DECLARATION OF CONFORMITY**

## HEINE Optotechnik GmbH & Co. KG Dornierstr. 6, 82205 Gilching, Germany

www.heine.com

Single Registration Number: DE-MF-000006269

## Accessory

Product family:

Headlights

Product group:

Polarisation filter

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.

Product name	P2 for ML4 LED	P2 for LoupeLight/MicroLight
Basic UDI-DI	4053755_H-A_02_TX	
GMDN		
UMDNS		
EMDN	Z129004	
Classification	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.

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)