



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: **Otosopes**
Product group: mini 3000

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	mini 3000 LED	mini 3000 F.O. LED
Basic UDI-DI	4053755_O_03_ZW	
GMDN	12849	
UMDNS	12-849	
EMDN	Z12149006	
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.

Gilching, 19 August 2024
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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Dornierstr. 6
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Dornierstr. 6, 82205 Gilching, Germany
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Single Registration Number: DE-MF-000006269

Medical device

Product family: Direct ophthalmoscopes
Product group: mini3000

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	mini3000	mini3000 LED
Basic UDI-DI	4053755_DO_03_46	
GMDN	46786	
UMDNS	12-817	
EMDN	Z12120114	
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, 12 July 2024
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)