



# 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:    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.

The otoscopes

<b>Product name</b>	mini3000	mini3000 F.O.	mini3000 F.O. LED
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<b>Basic UDI-DI</b>	4053755_O_03_ZW
<b>GMDN</b>	12849
<b>UMDNS</b>	12-849
<b>EMDN</b>	Z12149006
<b>Classification</b>	Class I according annex VIII

with the associated power sources as parts of the medical devices

<b>Battery handle</b>	mini3000
<b>Rechargeable handle</b>	mini3000

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, 27 July 2023  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)