



EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
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Single Registration Number: DE-MF-000006269

Medical device

Product family: Otoscopes
Product group: G100

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

Product name	G100 LED	G100
Basic UDI-DI	4053755_O_04_24	
GMDN	12849	
UMDNS	12-849	
EMDN	Z12149006	
Classification	Class I according annex VIII	

with the associated power sources as parts of the medical devices

Battery handle	BETA	BETA SLIM	Large
Rechargeable handle	BETA NT	BETA SLIM NT	BETA 4 USB
	BETA L	BETA 4SLIM NT	BETA 4 NT
Wall unit	EN 200	EN 200-1	

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.

Gilching, 27 July 2023
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)

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