

## **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:

**Otoscopes** 

Product group:

Disposable Tips

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	AllSpec	- , , ,
Basic UDI-DI	4053755_O-A_02_XN	40 - 40 - 60
GMDN	34897	
UMDNS	13-662	
EMDN	Z12149006	
Classification	Class I according annex VIII	C 1.000000 AND



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)