# OB-730-58\_Konformitätserklärung für Medizinprodukte EN 04

# HEINE

### **EU DECLARATION OF CONFORMITY**

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

www.heine.com

Single Registration Number: DE-MF-00006269

### Medical device

Product family:

**Dermatoscopes** 

Product group:

**DELTA** 

We hereby declare, under our sole responsibility, the conformity of the following product 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	DELTA 30 PRO	
Basic UDI-DI	4053755_D_01_VX	
GMDN	18021	
UMDNS	18-021	
EMDN	Z12040108	
Classification	Class I according annex VIII	



HEINE Optotechnik GmbH & Co. KG hereby declares that the product 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, 01 December 2025

(Place and date of issue)

Thomas Sauerer / PRRC (Name/function and signature)