



# 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: 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.

The dermatoscope

<b>Product name</b>	DELTA 20 T
<b>Basic UDI-DI</b>	4053755_D_02_W2
<b>GMDN</b>	18021
<b>UMDNS</b>	18-021
<b>EMDN</b>	Z12040108
<b>Classification</b>	Class I according annex VIII

with the appropriate power sources as part of the medical devices

<b>Battery handles</b>	BETA	BETA SLIM	Large
<b>Rechargeable handles</b>	BETA NT	BETA SLIM NT	BETA 4 USB
	BETA L	BETA 4SLIM NT	BETA 4 NT
<b>Wall transformer</b>	EN 200	EN 200-1	

is a class I medical device.





HEINE Optotechnik GmbH & Co. KG hereby declares that the product covered by this declaration is 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, 07 September 2023  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)