



# EU DECLARATION OF CONFORMITY

**HEINE Optotechnik GmbH & Co. KG**  
**Dornierstr. 6, 82205 Gilching, Germany**  
www.heine.com

Single Registration Number: DE-MF-000006269

## DERMATOSCOPES

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The dermatoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
DELTAone	4053755_D_01_VX	18021	18-021
DELTA 30			
DELTA 20T			
iC1			
mini3000 LED			
mini3000			

and

mini3000 battery handle	4053755_BH_01_YN	--	16-337
BETA battery handle			
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79	--	16-337
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
mini3000 rechargeable handle	4053755_WT_01_DE	16933	16-935
EN 200 wall transformer			
EN 200-1 wall transformer			

The dermatoscopes are class I according to the risk classification of Annex VIII.




References to any common specifications: N/A

This declaration of conformity is valid until a revised declaration of conformity is issued.

**HEINE OPTOTECHNIK**  
**GmbH & Co. KG**  
Dornierstr. 6  
82205 Gilching

Gilching, 20 January 2022  
(Place and date of issue)

  
Thomas Sauerer / PRRC  
(Name/function and signature)



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## ACCESSORIES

We hereby declare, under sole responsibility, that the contact plates and the disposable tubes covered by the present EU declaration of conformity are in accordance with the MDD 93/42/EEC.

### For Dermatoscopes

Product name	Basic UDI-DI	GMDN	UMDNS
DELTAone contact plate	4053755_D-A_01_RQ	--	--
DELTA 30 contact plate			
iC1 contact plate			
DELTA 20T contact plate			
mini3000 contact plate			
mini3000 LED contact plate			

### For proctological instruments

Product name	Basic UDI-DI	GMDN	UMDNS
UniSpec Disposable Tubes for Sigmoidoscope	4053755_PI-A_01_DR	--	--
UniSpec Disposable Tubes for Proctoscopes			
UniSpec Disposable Tubes for Anoscopes			

The contact plates and the disposable tubes are class I and meet all the applicable provisions set out in the directive 93/42/EEC according Annex VII.




This declaration of conformity is valid until a revised declaration of conformity is issued.

According to article 120 section 3 of the MDR (EU) 2017/745, a transition period for the contact plates and the tubes is available. The contact plates and the tubes could be placed on the market until 26 May 2024 under the directive 93/42/EWG.

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Gilching, 20 January 2022  
(Place and date of issue)

  
Thomas Sauerer / Director of Quality  
(Name/function and signature)