

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:

Dermatoscopes

Product group:

Contact plates

We hereby declare, under our sole responsibility, the conformity of the following products in accordance with the MDD 93/42/EEC

Product name	DELTAone	DELTA 30
Basic UDI-DI	4053755_D-A_01_RQ	
GMDN		
UMDNS		
EMDN	Z12040108	
Classification	Class I according annex IX	



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:

MDD 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 is available. The contact plates could be placed on the market until 26 May 2024 under the directive 93/42/EEC.

Gilching, 11 September 2023

(Place and date of issue)

Thomas Sauerer / PRRC

(Name/function and signature)

HEINE OPTOTECHNIK GmbH & Co. KG

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