



EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
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Single Registration Number: DE-MF-000006269

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.

HEINE OPTOTECHNIK
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Dornierstr. 6
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Gilching, 20 January 2022
(Place and date of issue)


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