

EC-Declaration of Conformity for medical devices
EG-Konformitätserklärung für Medizinprodukte
according to annex VII of Council Directive 93/42/EEC

We hereby declare that the medical device

HEINE DELTA® 20 Plus

UMDNS-Code: 18-021 | GMDN-Code: -

Epiluminescence microscope (Dermatoscope) with optional polarizing filter and accessory
Epilumineszenz Mikroskop (Dermatoskop) mit optionalem Polarisationsfilter und Zubehör

in the following configurations:

<u>Name or Type of device</u>	<u>REF-/Article-/Catalog-Number</u>
HEINE DELTA® 20 Plus Dermatoscope Head	K-008.34.210, K-008.34.212, K-008.34.213, K-008.34.214, K-008.34.215
HEINE DELTA® 20 Plus P Sets for polarisation	K-258.10.118, K-258.20.376, K-258.20.420, K-258.27.376, K-258.29.420
HEINE DELTA® 20 Plus N Sets for immersion	K-257.10.118, K-257.20.376, K-257.20.420, K-257.27.376, K-257.29.420
HEINE DELTA® 20 Plus Sets for polarisation and immersion	K-260.10.118, K-260.20.376, K-259.29.420

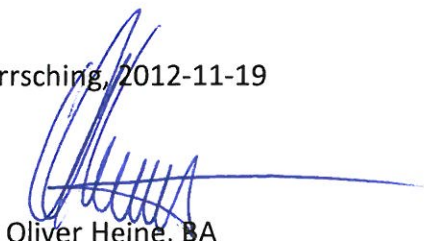
complies with

Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

This declaration of conformity refers to the products marketed since 2012-11-19 and is valid until a revised declaration of conformity is issued but not longer than 2016-02-01 (expiry date of the EN ISO 13485 certificate).



Herrsching, 2012-11-19



Oliver Heine, BA
- President & CEO -