



Certificate

No. Q5 106871 0003 Rev. 02

Holder of Certificate: **Heidelberg Engineering GmbH**
Max-Jarecki-Strasse 8
69115 Heidelberg
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, manufacture, final inspection, distribution and service of**
- Ophthalmic diagnostic devices
- Sterile protective caps (TomoCap)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 106871 0003 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_106871_0003_Rev.02)

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Valid from: 2024-01-14

Valid until: 2027-01-13

Date, 2023-11-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Heidelberg Engineering GmbH**
Max-Jarecki-Strasse 8, 69115 Heidelberg, GERMANY

Design and development, manufacture, final inspection,
distribution and service of

- Ophthalmic diagnostic devices
- Sterile protective caps (TomoCap)

Heidelberg Engineering GmbH
Rapsacker 1, 23556 Lübeck, GERMANY

Design and development and manufacture of

- Components for ophthalmic diagnostic devices

Heidelberg Engineering Ltd.
55 Marlowes, Hemel Hempstead, HP1 1LE, UNITED KINGDOM

Distribution and service of

- Ophthalmic diagnostic devices
- Sterile protective caps (TomoCap)