DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 074765 0017 Rev. 00

Holder of Certificate: **Bioptigen Inc.**
633 Davis Drive, Suite 480
Morrisville NC 27560
USA

Facility(ies): Bioptigen Inc.
633 Davis Drive, Suite 480, Morrisville NC 27560, USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution, Installation and Servicing of Ophthalmic Imaging Systems**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: 72140796

Valid from: 2019-04-12
Valid until: 2020-11-13

Date, 2019-04-12

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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