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ZLG-BS-244.10.08

TÜV SÜD Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 074765 0018 Rev. 00**

**Manufacturer:** **Bioptigen Inc.**
633 Davis Drive, Suite 480
Morrisville NC 27560
USA

**EC-Representative:** Leica Microsystems (Schweiz) AG
Max Schmidheiny Str. 201, 9435 Heerbrugg, SWITZERLAND

**Product Category(ies):** **Ophthalmic Imaging System using Optical Coherence Tomography**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713158400

**Valid from:** 2019-07-15
**Valid until:** 2021-11-13

**Date,** 2019-07-15

Stefan Preiß
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Facility(ies):**

Bioptigen Inc.
633 Davis Drive, Suite 480, Morrisville NC 27560, USA


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