

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bavaria Medizin Technologie GmbH
Argelsrieder Feld 8
82234 Weßling
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacturing, and distribution
of angioplasty catheters as well as design and
development and manufacturing of stent delivery systems and
catheters (see attachment for additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-03-31
Certificate Registration No.: SX 60117847 0001
An audit was performed. Report No.: 21208055 007
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-03-29



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Dipl.-Ing. F. Bley

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60117847 0001
Report No.: 21208055 007

Organization: Bavaria Medizin Technologie GmbH
Argelsrieder Feld 8
82234 Weßling
Deutschland

Scope:

Sites included:

Bavaria Medizin Technologie Romania S.R.L.
DJ. 106B, Km 1,75
Com Cristian, Cod 557085
Jud.Sibiu, Romania

Activities associated with the manufacturing of catheters

Certification Body



Date: 2017-03-29



F. Bley
Dipl.-Ing. F. Bley