EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60092283 0001

Report No.: 21208055 001

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

Products: Angioplasty catheters

(see attachment for additional sites included)

Expiry Date: 2019-03-30

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2014-03-31

Date: 2014-03-31

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60092283 0001
Report No.: 21208055 002

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

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 angioplasty catheters

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2014-08-22

Dr. K. Kluge