EC Certificate

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

TÜVRheinland®

Registration No.: HD 60147078 0001

Report No.: 17054672 002

Manufacturer:
BrosMed Medical Co., Ltd.
15th Building, SMEs Venture Park
Songshan Lake, Hi-Tech Industrial
Development Zone
523808 Dongguan, Guangdong
P.R. China

Products:
Medical Devices

(see attachment for products included)

Expiry Date: 2024-05-26

Digitally sign
Date: 2021.0
Reason: Mol
Location: Mo

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: 2020-04-24

Date: 2020-04-24

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
III
Zertifizierungsstelle

Wenxiang Zhang

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.

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147078 0001
Report No.: 17054672 002

Manufacturer:
BrosMed Medical Co., Ltd.
15th Building, SMEs Venture Park
Songshan Lake, Hi-Tech Industrial Development Zone
523808 Dongguan, Guangdong
P.R. China

Products:

-Introducer Sheath Sets
-Connecting Tubings
-Angiographic Syringes and Accessories
-Introducer Needles
-Non-vascular Guide Wires

Aspects of manufacture concerned with securing and maintaining sterile conditions:

-Balloon Inflation Devices
-Radial Artery Tourniquets
-Y Connector Sets
-Dose-control Syringes
-Manifolds

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland III Zertifizierungsstelle

Wenxiang Zhang

Date: 2020-04-24