

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: **BrosMed Medical Co., Ltd**
15th Building, SMEs Venture Park
SongShan Lake Hi-Tech Industrial
Development Zone
Dongguan
Guangdong
523808
China

广东博迈医疗器械有限公司
中国
广东省
东莞市
松山湖高新技术产业开发区北部
工业城中小科技企业创业园
第15栋
邮编: 523808

Holds Certificate No: **MD 647941**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and distribution of PTCA Coronary Balloon Dilatation Catheters, PTA Balloon Dilatation Catheters, Hydrophilic Guide Wires, Catheter Sheath Introducer and Accessories.

PTCA冠脉球囊扩张导管、PTA外周球囊扩张导管、亲水导丝、导管鞘及配件的设计、制造与销售。



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-08-22

Latest Revision Date: 2020-04-17

Effective Date: 2019-08-22

Expiry Date: 2022-08-21

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Location

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Registered Activities

Design, manufacture and distribution of PTCA Coronary Balloon Dilatation Catheters, PTA Balloon Dilatation Catheters, Hydrophilic Guide Wires, Catheter Sheath Introducer and Accessories.
PTCA冠脉球囊扩张导管、PTA外周球囊扩张导管、亲水导丝、导管鞘及配件的设计、制造与销售。

BrosMed Medical B.V.
Mgr. Buckxstraat 8
6134 AP Sittard
The Netherlands

Control of design and manufacture of PTCA Coronary Balloon Dilatation Catheters, PTA Balloon Dilatation Catheters and Hydrophilic Guide Wires.
Distribution of PTCA Coronary Balloon Dilatation Catheters, PTA Balloon Dilatation Catheters, Hydrophilic Guide Wires, Catheter Sheath Introducer and Accessories.

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780
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