

# 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:

**Stewart Brain, Head of Compliance & Risk - Medical Devices**

Original Registration Date: 2016-08-22

Effective Date: 2019-08-22

Latest Revision Date: 2019-06-13

Expiry Date: 2022-08-21



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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](https://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](https://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Certificate No: **MD 647941**

Location

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第15栋  
邮编: 523808

BrosMed Medical B.V.  
Hogebrinkerweg 31-33  
Hoevelaken  
3871 KM  
The Netherlands

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。

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



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