

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: Breas (Shanghai) Medical Technology Co., Ltd.
兹证明 Room 303, Floor 3, Building 6
No.8, Lane 449 of Nujiangbei Rd.
Putuo District
Shanghai
200333, China

博毅雅（上海）医疗科技有限责任公司
91310115MA1K423N1B
中国
上海
普陀区
怒江北路449弄8号
6幢3楼303室
邮编：200333

Holds Certificate No: **MD 709074**
持有证书

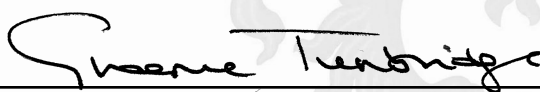
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

并运行符合 ISO 13485:2016 要求的质量管理体系，认证范围如下：

Design and Development, Manufacturing, Service and Distribution of Respiratory Therapy Devices including Sleep Apnea devices and all associated accessories. Service and Distribution of Respiratory Monitoring Systems, and Humidifier Devices.

呼吸治疗设备（包括睡眠呼吸暂停治疗设备）及所有相关附件的设计、开发、制造、服务和销售；呼吸监测系统和湿化设备的服务和销售。

For and on behalf of BSI:
BSI代表：


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期：2019-09-18

Latest Revision Date 最新发证日期：2025-07-11

Effective Date 生效日期：2025-09-18

Expiry Date 有效期至：2028-09-17



Page: 1 of 3

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束

An electronic certificate can be authenticated [online](http://www.bsi-global.com/ClientDirectory). 可以 [在线](http://www.bsi-global.com/ClientDirectory) 查询电子证书的有效性。

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

打印的证书可以通过网站 <http://www.bsi-global.com/ClientDirectory> 或者致电 +86 10 8507 3000 查询。

The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn)

本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.

信息查询及联系方式: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话: + 44 345 080 9000 BSI保证英国有限公司, 注册地英国, 注册号码7805321, 地址: 389 Chiswick High Road, London W4 4AL, UK.

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 709074**
持有证书:

Location 地点	Registered Activities 认证活动
Breas (Shanghai) Medical Technology Co., Ltd. Room 303, Floor 3, Building 6 No.8, Lane 449 of Nujiangbei Rd. Putuo District Shanghai 200333, China 博毅雅（上海）医疗科技有限责任公司 91310115MA1K423N1B 中国 上海 普陀区 怒江北路449弄8号 6幢3楼303室 邮编：200333	Design and Development, Service and Distribution of Respiratory Therapy Devices including Sleep Apnea devices and all associated accessories. Service and Distribution of Respiratory Monitoring Systems, and Humidifier Devices. 呼吸治疗设备（包括睡眠呼吸暂停治疗设备）及所有相关附件的设计、开发、服务和销售；呼吸监测系统和湿化设备的服务和销售。
Hainan Fosun Breas Medical Technology Co., Ltd. 1 Floor, Plant B, Cross-border E-commerce Industrial Park, Chengmai County Haikou Comprehensive Bonded Zone Haikou Free Trade Zone Hainan 571923, China 海南复星博毅雅医疗技术有限公司 91460000MA5TTB0B0G 中国 海南省 海口市保税区 澄迈县 海口综合保税区 跨境电商产业园B厂1层 邮编：571923	Design and Development, Manufacturing of Respiratory Therapy Devices and all associated accessories. 呼吸治疗设备及所有相关附件的设计、开发、制造。

Original Registration Date 首次发证日期： 2019-09-18
Latest Revision Date 最新发证日期： 2025-07-11

Effective Date 生效日期： 2025-09-18
Expiry Date 有效期至： 2028-09-17

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束
An electronic certificate can be authenticated [online](#). 可以 [在线](#) 查询电子证书的有效性。
Printed copies can be validated at [www.bsi-global.com/ClientDirectory](#) or telephone +86 10 8507 3000.
打印的证书可以通过网站 [http://www.bsi-global.com/ClientDirectory](#)或者致电 +86 10 8507 3000 查询。
The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration ([www.cnca.gov.cn](#))
本证书信息亦可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](#)) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话: + 44 345 080 9000 BSI保证英国有限公司, 注册地英国, 注册号码7805321, 地址: 389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 709074**
持有证书:

Location 地点	Registered Activities 认证活动
Hainan Fosun Breas Medical Technology Co., Ltd. No.402-1, 404-1, 406-1, 408-1 of International Commerce Center Cross-border E-commerce Industrial Park, Chengmai County Haikou Comprehensive Bonded Zone, Haikou Free Trade Zone Hainan 571923, China 海南复星博毅雅医疗技术有限公司 91460000MA5TTB0B0G 中国 海南省 海口市保税区 澄迈县 海口综合保税区跨境电商产业园 国际商务中心402-1、404-1、406-1、408-1室 邮编: 571923	Registered address with provision of a business registration address for Chinese legislative purposes. 获证组织注册地址。



Original Registration Date 首次发证日期: 2019-09-18

Latest Revision Date 最新发证日期: 2025-07-11

Effective Date 生效日期: 2025-09-18

Expiry Date 有效期至: 2028-09-17

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. 此证书的所有权属于BSI并受合同条款的约束
An electronic certificate can be authenticated [online](#). 可以 [在线](#) 查询电子证书的有效性。
Printed copies can be validated at [www.bsi-global.com/ClientDirectory](#) or telephone +86 10 8507 3000.
打印的证书可以通过网站 [http://www.bsi-global.com/ClientDirectory](#)或者致电 +86 10 8507 3000 查询。
The information of this certificate can also be found on the official website of the National Certification and Accreditation Administration ([www.cnca.gov.cn](#))
本证书信息亦可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](#)) 上查询。
The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
获证组织必须定期接受监督审核并经审核合格此证书方继续有效。
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
信息查询及联系方式: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. 电话: + 44 345 080 9000 BSI保证英国有限公司, 注册地英国, 注册号码7805321, 地址: 389 Chiswick High Road, London W4 4AL, UK.
China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。