

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 662148**
Issued To: **Shenzhen Medoo Medical Tech. Co., Ltd.**
Room 401, A407-B402, B415-B420
Platform Building, Key Laboratory, Virtual University Park
Yuexing 2 Road, Yuehai Street
Nanshan District, Shenzhen
Guangdong
518057
China

In respect of:

MECROSS CTO PTCA balloon catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-03-15**

Date: **2021-05-18**

Expiry Date: **2024-03-14**

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Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 662148

Issued To:

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 Guangdong
 518057
 China**

Intended Purpose as per the Instructions for Use:

The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Classification: Class III

Catalogue Number	Device Name	Model, Type
MC-01-1010	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1015	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1020	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1030	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1210	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1215	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1220	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1230	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1510	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1515	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1520	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1530	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1710	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO

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Nanshan District, Shenzhen
Guangdong
518057
China**

Catalogue Number	Device Name	Model, Type
MC-01-1715	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1720	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-1730	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2010	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2015	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2020	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2030	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2210	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2215	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2220	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2230	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2510	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2515	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2520	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2530	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2710	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2715	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-2720	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO

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 Guangdong
 518057
 China**

Catalogue Number	Device Name	Model, Type
MC-01-2730	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3010	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3015	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3020	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3030	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3210	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3215	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3220	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3230	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3510	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3515	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3520	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-3530	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-4010	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-4015	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-4020	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO
MC-01-4030	MeCross CTO PTCA Balloon Dilatation Catheter	MeCross CTO

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Certificate History

Date	Reference Number	Action
15 March 2019	8621007	First Issue.
15 March 2019	9631476	Traceable to NB 0086.
Current	3118922	Update to legal manufacturer's address. Addition of new EtO sterilization location (Jiangsu Medoo Medical Equipment Technology Co., Ltd., (Century Avenue, Dongkan Town)), including review of sterilization cycle parameters changes. Update to device labelling (multi-language IFU, addition of manufacturing site). Administrative update to supplementary information table, including administrative update to device intended use.

First Issued: **2019-03-15**

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Expiry Date: **2024-03-14**

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 662150
Issued To: Shenzhen Medoo Medical Tech. Co., Ltd.
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Platform Building, Key Laboratory, Virtual University Park
Yuexing 2 Road, Yuehai Street
Nanshan District, Shenzhen
Guangdong
518057
China

In respect of:

MECROSS NC PTCA balloon catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-03-15**

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Guangdong
518057
China**

Intended Purpose as per the Instructions for Use:

The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Balloon dilatation of a stent after implantation.

Classification: Class III

Catalogue Number	Device Name	Model, Type
MC-02-2008	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2010	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2012	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2015	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2018	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2208	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2210	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2212	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2215	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2218	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC

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 Guangdong
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Catalogue Number	Device Name	Model, Type
MC-02-2508	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2510	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2512	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2515	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2518	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2708	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2710	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2712	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2715	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-2718	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3008	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3010	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3012	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3015	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3018	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC

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 518057
 China**

Catalogue Number	Device Name	Model, Type
MC-02-3208	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3210	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3212	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3215	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3218	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3508	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3510	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3512	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3515	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3518	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3708	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3710	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3712	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3715	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-3718	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC

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 Guangdong
 518057
 China**

Catalogue Number	Device Name	Model, Type
MC-02-4008	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4010	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4012	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4015	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4018	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4508	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4510	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4512	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4515	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-4518	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-5008	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-5010	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-5012	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC
MC-02-5015	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC

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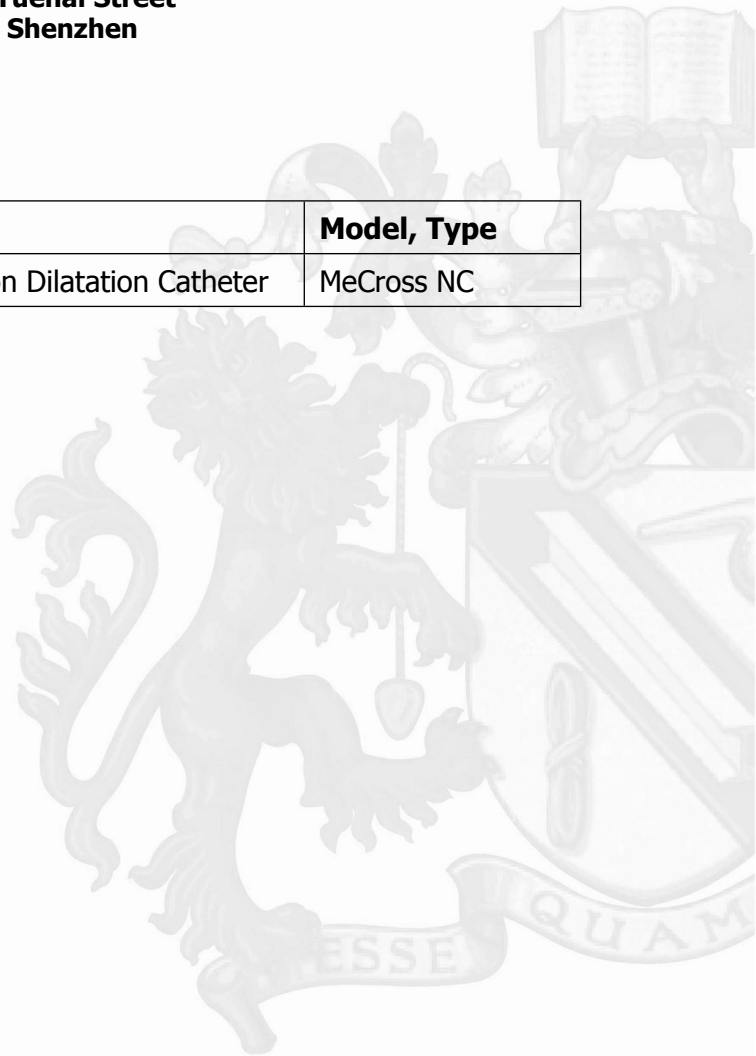
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Nanshan District, Shenzhen
Guangdong
518057
China**

Catalogue Number	Device Name	Model, Type
MC-02-5018	MeCross NC PTCA Balloon Dilatation Catheter	MeCross NC



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Guangdong
518057
China**

Certificate History

Date	Reference Number	Action
15 March 2019	8621011	First issue.
15 March 2019	9631476	Traceable to NB 0086.
Current	3118922	Update to legal manufacturer's address. Addition of new EtO sterilization location (Jiangsu Medoo Medical Equipment Technology Co., Ltd., (Century Avenue, Dongkan Town)), including review of sterilization cycle parameters changes. Update to device labelling (multi-language IFU, addition of manufacturing site). Administrative update to supplementary information table, including administrative update to device intended use.

First Issued: **2019-03-15**

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Expiry Date: **2024-03-14**

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certificate of Registration

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

This is to certify that:

Shenzhen Medoo Medical Tech. Co., Ltd. Room 401, A407-B402, B415-B420 Platform Building, Key Laboratory, Virtual University Park Yuexing 2 Road, Yuehai Street Nanshan District, Shenzhen Guangdong 518057 China	深圳脉动医学技术有限公司 中国 广东省 深圳市南山区 粤海街道高新区社区粤兴二道1号 虚拟大学园重点实验室平台大楼 401、A407-B402、B415-B420 邮编：518057
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Holds Certificate No: **MD 662153**

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

The design, development, manufacture and distribution of sterile, single-use PTCA balloon dilatation catheters.

一次性冠状动脉球囊扩张导管的设计、开发、生产与销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-07-03

Latest Revision Date: 2021-05-24

Effective Date: 2020-07-03

Expiry Date: 2023-07-02

Page: 1 of 3



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Certificate No: **MD 662153**

Location

Shenzhen Medoo Medical Tech. Co., Ltd.
Room 401, A407-B402, B415-B420
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Yuexing 2 Road, Yuehai Street
Nanshan District, Shenzhen
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518057
China

深圳脉动医学技术有限公司
中国
广东省
深圳市南山区
粤海街道高新区社区粤兴二道1号
虚拟大学园重点实验室平台大楼
401、A407-B402、B415-B420
邮编: 518057

Jiangsu Medoo Medical Equipment
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No.01, Shiji Road
Binhai Economic Development Zone
Industrial Park, Yancheng
Jiangsu
224500
China

江苏脉动医疗器械科技有限公司
中国
江苏省
盐城市
滨海经济开发区工业园
世纪大道1号
智汇园创新大厦3楼
邮编: 224500

Registered Activities

The distribution of sterile, single-use PTCA balloon dilatation catheters.

一次性冠状动脉球囊扩张导管的销售。

The design, development and manufacture of sterile, single-use PTCA balloon dilatation catheters.

一次性冠状动脉球囊扩张导管的设计, 开发和生产。

Original Registration Date: 2017-07-03

Latest Revision Date: 2021-05-24

Effective Date: 2020-07-03

Expiry Date: 2023-07-02

Page: 2 of 3

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 662153**

Location

Jiangsu Medoo Medical Equipment
Technology Co., Ltd.
No.32 Century Avenue
Dongkan Town
Binhai County
Yancheng
Jiangsu
224500
China

江苏脉动医疗器械科技有限公司
中国
江苏省
盐城市
滨海县
东坎镇
世纪大道32号
邮编: 224500

Registered Activities

The sterilization of single-use PTCA Balloon Dilatation
Catheters.
一次性冠状动脉球囊扩张导管的灭菌。



Original Registration Date: 2017-07-03

Latest Revision Date: 2021-05-24

Effective Date: 2020-07-03

Expiry Date: 2023-07-02

Page: 3 of 3

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
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