



Certificate

No. Q5 073322 0011 Rev. 00

Holder of Certificate: **Beijing Target Medical Technologies Inc.**

No.60, Shunren Rd.
Shunyi District
101300 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Beijing Target Medical Technologies Inc.
No.60, Shunren Rd., Shunyi District, 101300 Beijing, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Service of Disposable Introducer Kit, Disposable Central Venous Catheter Kit, Introducer needle, Disposable Blood Pressure Transducer, Arterial Blood Sampling Kits.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ18711041

Valid from: 2019-04-01

Valid until: 2022-03-31

Date, 2019-03-29

Stefan Preiß

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 73322 014

Manufacturer: **Beijing Target Medical Technologies Inc.**

No.60, Shunren Rd.
Shunyi District
101300 Beijing
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Lepu Medical (Europe) Cooperatief U.A.**

Abe Lenstra Boulevard 36
8448 JB Heerenveen
THE NETHERLANDS

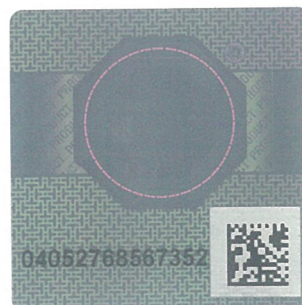
Product: **Catheter for Cardiology and Angioplasty
Disposable central venous catheter kit**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: BJ1771106

Valid from: 2018-04-09

Valid until: 2020-09-26



Date, 2018-04-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate**EC Design-Examination Certificate**Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 73322 014

Model(s): Disposable central venous catheter kit**Parameters:**

Size Range:

Single Lumen: 14G-20G(OD:1.05-2.1mm)

Double Lumen: 4F-11.5F(OD:1.35-3.85mm)

Triple Lumen: 5.5F-7F(OD:1.85-2.35mm)

Length of Tubing: 50-600mm

Facility(ies):Beijing Target Medical Technologies Inc.
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