

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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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.

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

REPUBLIC OF CHINA