



得泰醫療衛生用品（蘇州）有限公司

DELTAI MEDICAL & HEALTH ARTICLES (SUZHOU) CO., LTD.

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KIT Declaration of Conformity

Manufacturer: DELTAI MEDICAL & HEALTH ARTICLES(SU ZHOU) CO.,LTD.

Manufacturer Add.: 88,FUDA RD.,LUDU,TAICANG SUZHOU,JIANGSU,215412 CHINA

European Rep.: inocare Medical GmbH

European Rep. Add.: Industriestr. 42, 74927 Eschelbronn, Germany

We DELTAI MEDICAL & HEALTH ARTICLES(SU ZHOU) CO.,LTD. hereby declare according with article 12 of the legislative decree 24th February 1997 n. 46 and further amendments regarding the medical devices (directives 93/42/CEE 1993/06/14 and further amendments), declare in our sole responsibility, to put on the market the following assembled kit:

Product Name/No.: SUCTION UNIT KIT: **28180**

Component List:

SUCTION UNIT: **DA-00750**

Class 1 M.D.

UNSTERILE COLLECTION JAR AND BOTTLE: **DA-00752**

Class 1 M.D.

UNSTERILE CATHETER 6 X 170 mm: **DA-00753**

Class 1 M.D.

UNSTERILE CATHETER 10 X 190 mm: **DA-00754**

Class 1 M.D.

We also declare that:

- We tested the mutual compatibility of the components and the correspondence to the existing legislations in accordance with the specifications/instructions of the different manufacturers;
- We checked the presence of the CE mark on each medical device according to the 93/42/ECC directive and further amendments issued by a notified body or upon self-declaration of the manufacturer;
- The packaging has been subject to suitable checks and includes the manufacturer informations and instructions.



Date: 2019.3.25

Deltai Medical & Health Articles (Suzhou) Co., Ltd.

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