



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 15 03 82107 007

Manufacturer: Zhejiang Runqiang Medical Instruments Co., Ltd

No. 618 Dade Road, Jiaxing Xiuzhou District
314031 Jiaxing City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product: Disposables for Anaesthesia and Respiration
Disposable Anaesthesia Needle and Anaesthesia 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.: BJ1479406

Valid from: 2015-07-31

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Date, 2015-08-03

Hans-Heiner Junker

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

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Model(s):

Disposable Anaesthesia Needle and Anaesthesia Kit

Parameters:

Epidural needle (AN-E),
diameters of 20~15G (0.9~1.8mm)
Effective lengths of 80 and 90mm.

Spinal needle (type I) AN-SI,
diameters of 27~15G(0.4~1.8mm)
Effective lengths of 38,58,75,88,
100,110 and 120mm.

Spinal needle (type I) AN-SI with introducer needle,
diameters of 27~15G(0.4~1.8mm)
Effective lengths of 38, 58,
75,88,100,110 and 120mm.

Spinal needle (type II) AN-SII,
diameters of 27~20G(0.4~0.9mm)
Effective lengths of 75, 88, 100, 110 and 120mm.

Spinal needle (type II) AN-SII with introducer needle,
diameters of 27~20G(0.4~0.9mm)
Effective lengths of 75, 88, 100, 110 and 120mm.

The epidural anaesthesia kit (AS-E)
diameters of 15-18G(1.2-1.8mm)
consists of an epidural needle, an epidural catheter,
an introducer guide, a catheter connector,
a liquid filter, a lor (Loss of resistance) syringe.

The spinal anaesthesia kit (AS-S) with
or without introducer needle,
diameters of 20-25G(0.5-0.9mm)
consists of a spinal needle (type I),
a liquid filter,a lor (Loss of resistance) syringe.

The Combined spinal and epidural
anaesthesia kit (AS-E/SII) With or
without needle,consists of
an epidural needle, a spinal needle (type II),
an epidural catheter, a introducer guide,
a catheter connector, a liquid filter,
a lor (Loss of resistance)syringe.

Thereinto, the epidural catheter
diameters:0.8mm and 1.0mm;
effective lengths >=900mm

Facility(ies):

Zhejiang Runqiang Medical Instruments Co., Ltd
No. 618 Dade Road, Jiaxing Xiuzhou District, 314031 Jiaxing City,
PEOPLE'S REPUBLIC OF CHINA