



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 04 82107 009

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.:

BJ1679406

Valid from:

2018-03-01

Valid until:

2022-12-11

**Date,** 2018-03-01

Stefan Preiß

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

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No. G7 17 04 82107 009**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 (with stylet made of
stainless steel or PP), an epidural catheter,
an introducer guide, a catheter connector,
a liquid filter (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

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 (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

The Combined spinal and epidural anaesthesia kit(AS-E/SII)
with or without introducer needle, consists of
an epidural needle (with stylet made of stainless steel
or PP), a spinal needle (type II),
an epidural catheter, a introducer guide,
a catheter connector, a liquid filter (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

Thereinto, the epidural catheter
diameters: 0.8mm and 1.0mm
Effective length of 900mm – 1200mm.

Facility(ies):

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