

## Confirmation Letter

**To:**

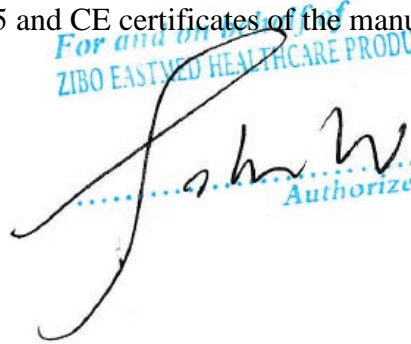
**Center for Public Procurement in Healthcare,  
Republic of Moldova**

WHEREAS,

We, Zibo Eastmed Healthcare Products Co., Ltd., who are manufacturers of Disposable Medical Products, having factories at No.118 Huaguang Road, Zhangdian District, Zibo Shandong, China,

confirm that Spinal Needle Quincke point type 18G, 19G and 20G (catalogue code DM-SN, Ref. 26067P, 26060P and 26053P), offered by SOGNO SRL company on the Tender no. 21054504, are manufactured by Zhejiang Runqiang Medical Instruments Co., Ltd. and are marketed by our company as an official distributor.

To this letter we attach the ISO 13485 and CE certificates of the manufacturer

For and on behalf of  
ZIBO EASTMED HEALTHCARE PRODUCTS CO., LIMITED  
  
Authorized Signature(s)

Date: 09.06.2022

# EC Certificate

## Full Quality Assurance System

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

No. G1 17 12 82107 013



Product Service

### 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 Category(ies):

**Disposable Anaesthesia Needle and Anaesthesia Kit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

### Report No.:

BJ1779407

### Valid from:

2018-05-07

### Valid until:

2023-05-06

Date, 2018-03-29

Stefan Preiß



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

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Product Service

**EC Certificate****Full Quality Assurance System**

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

**No. G1 17 12 82107 013****Facility(ies):**

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



# Declaration of Conformity



Manufacturer:

Zhejiang Runqiang Medical Instruments Co., Ltd.  
No. 599 Ruifeng Street, Gaozhao District, Xiuzhou District  
314031 Jiaxing City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

TEL: +86-573-82287088, +86-573-82287018  
FAX: +86-573-82287098

Medical Device:

Disposable Anaesthesia Needle And Anaesthesia Kit

Classification - Annex IX:

class III, Rule 7

Conformity assessment Route:

Annex II .3+ II.4

We, Zhejiang Runqiang Medical Instruments Co., Ltd., herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices,  
as amended by 2007/47/EEC;

All supporting documentation is retained at the premises of the manufacturer.  
We, as the manufacturer, are exclusively responsible for the declaration of conformity.

Standards applied: Related applicable harmonized STANDARDS (published in the official journal of the european communities)

Notified Body:

TÜV SÜD Product service GmbH  
Ridlerstr 65, D-80339 München, Germany

identification number

**CE** 0123

(EC) Certificate(s):

G7 17 04 82107 009  
G1 17 12 82107 013



European Representative: Shanghai International Holding Corp. GmbH(Europe)  
Eiffestrasse,80,20537,Hamburg,Germany Tel:0049-40-2513175, Fax :0049-40-255726

Start of CE-marking:

Date of first CE marking ( 2012-12-12)

Place, Date of Declaration:

JIAXIANG CITY, 2022-05-05

Signature:

Name: MR Fangming Xu

I behalf of Zhejiang runqiang medical Instruments Co.,Ltd

Position: Management representative