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

Digitally signed by Iarovoi Petru
Date: 2022.06.09 10:58:04 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

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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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Declaration of Conformity

Manufacturer:	Zhejiang Runqiang Medical Instruments Co. , Ltd. No. 599 Ruifeng Street, Gaozhao District, Xiuzhou District 314031 Jiaxing City, Zhejiang Proyince 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

EC REP

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