ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 103129 0002 Rev. 00

Manufacturer:

Shandong Chengwu Medical Products Factory
Southern end of Quancheng Road
Chengwu County
274200 Heze City, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable sterile venous blood specimen collection needle, Disposable infusion set.

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

Report No.: BJ1776601_BJ19766011

Valid from: 2019-12-06
Valid until: 2024-02-22

Digitally signed by Ionaşcu Andrei
Date: 2023.08.24 13:33:49 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2019-12-06

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD

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No. G2 103129 0002 Rev. 00

Facility(ies):

Shandong Chengwu Medical Products Factory
Southern end of Quancheng Road, Chengwu County, 274200
Heze City, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

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Compliance Report

Applicant:	Shandong Chengwu Medical Products Factory
Address:	Southern End of Quancheng Road, Chengwu County, 274200 Heze City, Shandong Province, P.R.China
Product:	Needle Holder, Urine Bag
Type:	See annex for details
Product Classification:	Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **03126**
Initial Issue Date: **24 Oct 2019**

Betty Bao

Signer

This report is the property of NQA and should be returned to NQA upon request.

Annex to Report (No. 03126)

Shandong Chengwu Medical Products Factory

Product Name	Type
Needle Holder	SD001, SD002
Urine Bag	100mL, 200mL, 500ml, 750ml, 1000ml, 1500mL, 2000mL, 2500mL, 4000mL

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.