



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

A handwritten signature in black ink that reads 'Betty Bao'.

Signer



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.

nqa