

Compliance Report

Applicant:

Jiangsu Huida Medical Instruments Co., Ltd.

Address:

Qingfeng Industrial Park, Yandong, Yancheng City, Jiangsu

Province, P. R. China.

Product:

Plastic products for medical use: Tube Stopper, Test Tube Racks, Slide Storage Boxes, Specimen Containers, Plastic Test Tube, Petri Dishes, Pipette Tips, Centrifuge Tubes, Embedding Cassettes, Freezing Tubes, Pasteur Pipettes, Loops, Cuvettes, Slide Mailers, Pipette Tip Boxes, Centrifuge Tube Boxes, I.D. Bracelets, Umbilical Cord Clams, Serological Pipettes.

Type:

See annex for details

Product Classification: Others

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 II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

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. 02130-1

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Tony Chen

General Manager (Signature)

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