

Compliance Report

Applicant:

TIANJIN AIXIN MEDICAL EQUIPMENT CO., LTD.

Address:

Block 3, No. 1 Yucheng Rd, Yangliuqing Town, Xiqing, Tianjin,

China 300380

Product:

Laser pinhole drilling unit

Type:

AX-88, AX-88A, AX-88B

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 Low Voltage Directive (2006/95/EC) and Electromagnetic Compatibility Directive (2004/108/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. 01968

Initial Issue Date: 17 Aug 2012

General Manager

(Signature)