



# Declaration of Conformity

The following product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC). The listed standards as below were applied:

The following Equipment:

Product : Headlight  
Model Number : HL8000  
Trade Name : Zumax

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC). For the evaluation regarding EMC, the following standards were applied:

## RFI Emission:

EN 60601-1-2: 2001 : Product family standard  
IEC 61000-3-2: 2005 : Limits for harmonic current emission  
IEC 61000-3-3: 2002 : Limitation of voltage fluctuation and flicker in low-voltage supply system

## Immunity:

EN 60601-1-2: 2001 : Product family standard

The following importer/manufacturer is responsible for this declaration:

Company Name : Zumax Medical Co., Ltd.  
Company Address : 9 Dengwei Road, Suzhou New District, Suzhou, Jiangsu Province, 215011, China  
Telephone : +86-512-66650100-504 Facsimile: +86-512-66650100-501

Person is responsible for marking this declaration:

Xiangdong Lu  
Name (Full Name)

CEO  
Position/ Title

Mar 16, 2007  
Date

Zhenming Wang  
Legal Signature

# CE Statement of Conformity

This certifies that the following designated product:

Product : Headlight  
Model Number : HL8000  
Trade Name : Zumax  
Company Name : Zumax Medical Co., Ltd.

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC). For the evaluation regarding EMC, the following standards were applied:

**RFI Emission:**

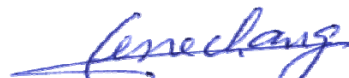
EN 60601-1-2: 2001 : Product family standard  
IEC 61000-3-2: 2005 : Limits for harmonic current emission  
IEC 61000-3-3: 2002 : Limitation of voltage fluctuation and flicker in low-voltage supply system

**Immunity:**

EN 60601-1-2: 2001 : Product family standard



TEST LABORATORY



Gene Chang /President

The verification is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab. Logo.