



DECLARATION OF CONFORMITY

Manufacturer: Konftec Corporation

Address: 12F-7, No. 77, Sec. 1, Sintai 5th Rd., Sijhih City, Taipei County, Taiwan

Product: Low Level Laser Therapy System

Trade Name: Konf

Model Numbers: Aculas-AM-X (X=100; 151; 102; 200; 201; 273; 320)

Aculas-HB-Y (Y=150; 250; 251; 750; 850; 950)

Klas-Z (Z= A, D, E, N, S)

Megalas-AM-800

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards. All supporting documentations are retained under the premise of manufacturer.

- Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical device (MDD 93/42/EEC)
- EN 60601-1-2: 2001 (EMC testing of Medical Electric Equipment)
EN 55011: 1998 + A1:1999 + A2:2002
(IEC 61000-4-2: 1995 + A1: 1998 + A2: 2000; IEC 61000-4-3: 2002 + A1: 2002;
IEC 61000-4-4: 1995 + A1: 2000 + A2: 2001; IEC 61000-4-5: 1995 + A1: 2000;
IEC 61000-4-6: 1996 + A1: 2000; IEC 61000-4-8: 1993 + A1: 2000;
IEC 61000-4-11: 1994 + A1: 2000)
- EN 61000-3-2: 2001
- EN 61000-3-3: 1995 + A1: 2001

The tests were performed by the following accredited test laboratory:

Compliance Certification Services Inc.

No. 165, Chung Sheng Road, Hsin Tien City, Taipei, Taiwan

Eric Lin

General Manager

Taipei, Taiwan

May 1, 2009

 **Konf** *The True Medicine*

EC- DECLARATION OF CONFORMITY



For the following equipment :

Equipment : emLas Laser System

Model Name: emLas

Applicant: Konftec Corporation

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 **EUROPEAN COUNCIL DIRECTIVE 93/42//EEC**. For the evaluation regarding the **93/42//EEC**, the following standards were applied :

EN 60601-1-2 : 2007

EN 61000-4-2 :1995

EN55011:2007

EN 61000-4-3 :2006

EN 61000-3-2:2006

EN 61000-4-4:2004

EN 61000-3-3:1995+corr.:1997

EN 61000-4-5:2006

EN 61000-4-6:2007

EN 61000-4-8:1993

EN 61000-4-11:2004

The following manufacturer/importer is responsible for this declaration :

Person responsible for marking this declaration :

Taipei, Taiwan

(Place)

Sep. 1. 2010

(Date)

(Signature)

EC- DECLARATION OF CONFORMITY



For the following equipment :

Equipment : Digital Honeycomb Laser Hood

Model Name: Megalas-HR-400

Applicant: Konftec Corporation

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 **EUROPEAN COUNCIL DIRECTIVE 93/42//EEC**. For the evaluation regarding the **93/42//EEC**, the following standards were applied :

EN 60601-1-2 : 2007

EN 61000-4-2 :1995

EN55011:2007

EN 61000-4-3 :2006

EN 61000-3-2:2006

EN 61000-4-4:2004

EN 61000-3-3:1995+corr.:1997

EN 61000-4-5:2006

EN 61000-4-6:2007

EN 61000-4-8:1993

EN 61000-4-11:2004

The following manufacturer/importer is responsible for this declaration :

Person responsible for marking this declaration :

Taipei, Taiwan

(Place)

Sep. 1. 2010

(Date)

(Signature)