



## DECLARATION OF CONFORMITY

### TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER: Shenzhen Emperor Electronic Technology Co., Ltd

Address: 2&3/F, Building15, No.1008 Songbai Road,  
Nanshan District, Shenzhen 51808, China

MEDICAL DEVICE: Full Digital Ultrasound Diagnostic Device

N5 UMDNS: 14278

Classification - Annex IX: class IIa, rule 10

Conformity assessment Route: Annex II.3

WE, Shenzhen Emperor Electronic Technology Co., Ltd , HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

EN ISO 13485:2003, EN ISO14971:2007, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, IEC 61157:2007, IEC 60878:2003, EN 1041:2008, EN 980:2008, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC60601-2-37:2007, IEC62304:2006, IEC60601-1-6:2006.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123  
(EC) CERTIFICATE(S): G1 11 06 49578 010

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Trading Corp. GmbH  
(Hamburg) (Europe)

Address: Eiffestrasse 80, 20537, Hamburg, Germany  
Telephone: 0049-40-2513175

DATE OF CE CERTIFICATE IS EXPIRED: 2014-10-20  
DATE OF CE CERTIFICATE WAS AFFIXED: 2011-08-19  
PLACE, DATE OF DECLARATION: Shenzhen, 2012-07-15  
SIGNATURE: *He Ping*  
DATE: 2012-07-15  
Position: Vice General Manager

