



## Declaration of Conformity

Manufacture Shantou Institute of Ultrasonic Instruments Co.,Ltd.  
Address #77, Jinsha Road, Shantou, S.E.Z., 515041, P.R.China.

European Representative Shanghai International Holding Corp. GmbH(Europe)  
Representative Eiffestrasse 80, 20537 Hamburg Germany

Product Category Medical Ultrasonic Diagnostic Systems  
Models Apogee 3500

Classification Digital Color Doppler Ultrasound Imaging System  
Ila based on MDD 93/42/EEC annex IX rule 10

The UMDNS code 14276

Conformity Assessment Route Annex II.3

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC). All the supporting documents and files are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH, Ridlestrasse. 65, 80339 München, Germany.

Certificate: G1 15 02 51640 008

Start of CE-Marking: 2005-1-29

Signature:

Date: 2015.04.29

Position: President

Place: Shantou

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Shantou Institute of Ultrasonic Instruments Co., Ltd.