



Declaration of Conformity

Manufacture Address	Shantou Institute of Ultrasonic Instruments Co.,Ltd. #77, Jinsha Road, Shantou, S.E.Z., 515041, P.R.China.
European Representative	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany
Product Category Models	Medical Ultrasonic Diagnostic Systems Apogee 3500 Digital Color Doppler Ultrasound Imaging System
Classification	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 manufactures.

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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