Hitachi Medical Corporation

MEDICAL SYSTEM OPERATION GROUP 2-1 SHINTOYOFUTA, KASHIWA-SHI, CHIBA 277-0804,JAPAN FAX: 81-4-7131-4162, PHONE: 81-4-7131-4151

EC-CONFORMITY DECLARATION

Manufacturer

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Tokyo, 101-0047 Japan

European Representative

Hitachi Medical Systems GmbH

Kreuzberger Ring 66

D-65205 Wiesbaden,

Germany

Medical Device

Model Name: Ultrasound Transducers/Probes

Model Number: EUP-L65 MDD Classification: IIa

Serial Number: AEE0302P200 and after

The undersigned hereby declares that the medical device as specified above and related options comply with the essential requirements of Annex I of the EC-Directive 93/42 EEC.

The declaration of conformity is based on a assessment procedure in compliance with the EC Directive 93/42 EEC, Annex II for a

Full Quality Assurance System

issued by:

TÜV Rheinland Product Safety GmbH

Am Grauen Stein D-51105 Köln

Germany

Ident No.:

CE-0197

Mar 2, 2005

T. Kawano

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Ultrasound Systems Division

N. Kawabe'

Department Manager

Quality Assurance Division