

MEDICAL SYSTEM OPERATION GROUP 2-1 SHINTOYOFUTA, KASHIWA-SHI, CHIBA 277-0804, JAPAN

EC-CONFORMITY DECLARATION

Manufacturer

Hitachi Medical Corporation

4-14-1, Soto-Kanda, Chiyoda-Ku

Tokyo, 101 0021 Japan

European Representative

Hitachi Medical Systems GmbH

Kreuzberger Ring 66

D-65205 Wiesbaden,

Germany

Medical Device

Modality: Transducer, Ultrasonic

UMDNS Code: 14-121

MDD Classification: IIa (rule 10) Model Name: Linear array Probe

Model Type: EUP-L53S

Serial No.: KE17631006 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 an assessment procedure in compliance with the EC Directive 93/42 EEC, Annex II for a Full Quality Assurance System.

Notified Body: TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg Germany

Ident No.:

CE-0197

K. Kuriyama

General Manager

Ultrasound System Division

Department Manager

1. Emale

QA Department

Place

Japan

Date

2010 - 9 - 29

Hitachi Medical Corporation MEDICAL SYSTEM OPERATION GROUP 2-1 SHINTOYOFUTA, KASHIWA-SHI, CHIBA 277-0804, JAPAN

Accessory

Coupler Attachment

EZU-PA3C1 (Option)

Coupler Attachment

EZU-PA3C1H (Option)

Coupler Attachment

EZU-PA3C2 (Option)