HITACHI

Hitachi Medical Corporation

MEDICAL SYSTEM OPERATIONS GROUP, KASHIWA
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
Otto von Guericke Ring 3,
D-65205 Wiesbaden, Germany

Medical Device

Modality	: Ultrasound Transducers / Probes
UMDNS Code	: 16-272
MDD Classification	: IIa (Rule 5)
Model Name	: Transrectal probe
Model Type	: EUP-U533

The first manufactured serial number: PE15911

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark, as documented in each in-process check list of the form No. SKM C2-147for manufacturing.

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

N. Kawabe
Division Manager
Quality Assurance Division

Place JAPAN

Date 2012-09-21

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Accessory

- Puncture Guide Fixture EZU-PA3U (Option)