

EU DECLARATION OF CONFORMITY

1. No. ECR-US-020-01-E

2. Name and address of the manufacturer and authorized representative:

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

3. This declaration of conformity is issued under the sole responsibility of the manufacture.

4. Object of the declaration

Product name in general: Ultrasound Transducer/Probe

Series name: EUP-C516

Category of RoHS Directive(ANNEX I): 8. Medical Devices

5. The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electric equipment.


6. Where applicable, references to the relevant harmonized standards used or references to the technical specifications in relation to which conformity is declared:

- EN 50581:2012


technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

7. Additional information:

Signature


N.Yoshida
Department Manager
Ultrasound Systems Design Office

Signature


N.kawabe
Division Manager
QA Division

Place and date of issue:

Place JAPAN Date 16 / 06 / 2014 (DD / MM / YYYY)

Table of product name in general:

- | | |
|---|-----------------------------------|
| 1 Ultrasound Transducers/Probes | 5 X-Ray CT Systems |
| 2 Ultrasound Diagnostic Systems | 6 Optical Encephalography Systems |
| 3 Sterile Puncture Adapters for Ultrasound Probes | 7 Mobile X-ray Units |
| 4 MRI Systems | 8 Radiographic Systems |