

## EC-DECLARATION OF CONFORMITY

Manufacturer: Hitachi, Ltd.  
Address: 2-16-1 Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan

selected conformity assessment procedure: Annex II excluding (4) RoHS Article 7 (b), Module A

EU Authorized representative: Hitachi Medical Ultrasound Logistics,  
Address: Zweigniederlassung der Hitachi Medical Systems Europe Holding AG  
Carl-Zeiss-Strasse 5  
D-72555 Metzingen  
Germany

Product: **VC34A Probe**

Model Code: **VC34A**

Classification (MDD, Annex IX): Ila Categories (RoHS( II ), Annex I): No.8

Classification rule (MDD, Annex IX): Rule 10

We herewith declare that the above mentioned products including all its accessories meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

General applicable directives:

**Medical Device Directive : Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (93/42/EEC as amended by 2007/47/EC; MDD).**

Standards : MDD Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product are :

EN 60601-1:2006/AC:2010, EN 60601-1-2:2007/AC:2010, EN 60601-2-37:2008  
EN 62366:2008(EN 60601-1-6:2010), EN 1041:2008, EN ISO 14971:2012  
EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5: 2009, EN 980:2008

Other Standards : EN ISO 10993-10:2009

Notified body : TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123  
Address (for MDD): Ridlerstraße 65, 80339 München, Germany

**RoHS Directive : Directive 2011/65/EU of 8 June 2011 concerning on the restriction of the use of certain hazardous substances in electrical and electronic equipment.**

Standards : RoHS Directive Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product is

EN 50581:2012

Production facility : **Hitachi Healthcare Manufacturing, Ltd. Kashiwa Factory**  
Address: **2-1, Shintoyofuta, Kashiwa-shi, Chiba-ken, 277-0804, Japan**

Starting of CE Marking: 204J1501

Date: **01. Apr. 2016**

Signature: 

Name of issuer : Ryosuke Maeda

Place: Tokyo, JAPAN

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Quality Assurance Department 1