

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 Systems GmbH**
Address: **Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany**

Product: **Transrectal Probe**

Model Code: **EUP- R54AW-33**

Classification (MDD, Annex IX): Ila Categories (RoHS(II), Annex I): No.8
Classification rule (MDD, Annex IX): Rule 5

Statement:

We are exclusively responsible for the declaration of conformity and herewith declare that the above mentioned products including all its options 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. Tokyo Works**
Address: **3-7-19 Imai, Ome-shi, Tokyo, 198-8577, JAPAN**

Starting of CE Marking: **20504387 and 20506352 and later**

Date: **Jan. 16. 2017**

Signature: 

Name of issuer : Ryosuke Maeda

Place: **Tokyo, JAPAN**

Position : Senior Manager
Quality Assurance Department 1