HITACHI
Inspire the Next

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:	***Ultrasound Diagnostic Scanner***
Model Code:	***HI VISION Preirus***
Classification (MDD, Annex IX):	Ⅱa Categories (RoHS(Ⅱ), Annex I): No.8
Classification rule (MDD, Annex IX):	rule 10

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 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 62304:2006:/AC: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 ISO 17664:2004, EN ISO 15223-1:2016

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: G31***01503***17～***(Including*** G31***01107***17***,*** G31***01453***17***,*** G31***01477***17***,*** G31***01478***17 ***and*** G31***01499***17***)***

Date: ***Dec. 27. 2017***

Signature: 

Name of issuer : Ryosuke Maeda Place: ***Tokyo, JAPAN***
Position : Management Representative