HITACHI
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EC-DECLARATION OF CONFORMITY

Manufacturer:	Hitachi, Ltd.
Address:	2-16-1,Higashi-Ueno Taito-ku Tokyo, Japan
selected conformity assessment procedure:	MDD:Annex II excluding (4), RE:Annex III (Module B), RoHS Article 7 (b), (Module A)
EU Authorized representative:	**Hitachi Medical Systems GmbH**
Address:	**Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany**
Product:	***Diagnostic Ultrasound System***
Model Code:	***ARIETTA Prologue***

Classification (MDD, Annex IX): IIa Categories (RoHS(II), Annex I): No.8 RE Directive : Annex III
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/A1:2013, 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 15223-1:2016

Other Standards :IEC 62079:2001, ISO 7010:2003/A6:2010, ISO 3864-2:2004, IEC 60601-1-9:2007

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

RE Directive : DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Standards : RE Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product are :
EN 300 328(V2.1.1), EN 301 893(V2.1.1) , EN 301 489-1(V2.1.1), EN 301 489-17(V3.1.1) , EN 62311:2008 , EN 50566:2013

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. Analytical Systems Kashiwa Factory***
Address: ***2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN***

Start of CE Marking: ***G3013236***

Date: ***Apr. 01. 2019***

Signature: 

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