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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:	***Diagnostic Ultrasound System***
Model Code:	***ARIETTA 60 (*Include attachment sheet)***
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 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 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

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***

Starting of CE Marking: ***G3010647***

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

Signature:

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

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Attachment sheet for Declaration of Conformity of ARIETTA 60.

This Declaration of Conformity is also effective to model variations of the following in addition to the original model.

ARIETTA V60 / ARIETTA S60

for corresponding to tailoring which uses system brand appropriately according to diagnosis region.

for Radiology:

ARIETTA 60 SE / ARIETTA V60 SE / ARIETTA S60 SE *SE: Standard Edition
ARIETTA 60 LE / ARIETTA V60 LE / ARIETTA S60 LE
ARIETTA 60 LE+ / ARIETTA V60 LE+ / ARIETTA S60 LE+ *LE: Limited Edition

for Cardiology:

ARIETTA 60 CV / ARIETTA V60 CV / ARIETTA S60 CV *CV: Cardiovascular

for Surgery:

ARIETTA 60 SURGERY / ARIETTA V60 SURGERY / ARIETTA S60 SURGERY
ARIETTA 60 INTRAOPERATIVE / ARIETTA V60 INTRAOPERATIVE /
ARIETTA S60 INTRAOPERATIVE
ARIETTA 60 PE / ARIETTA V60 PE / ARIETTA S60 PE *PE: Premium Edition

for Primary Care:

ARIETTA 60 PC / ARIETTA V60 PC / ARIETTA S60 PC

for EUS:

ARIETTA 60 ENDOSCOPIC / ARIETTA V60 ENDOSCOPIC / ARIETTA S60 ENDOSCOPIC

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