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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 70 (*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: ***G3006277***

Date: ***Apr. 18. 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 70.

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

ARIETTA V70 / ARIETTA S70
ARIETTA 70a / ARIETTA S70a / ARIETTA V70a

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

for Radiology:

ARIETTA 70 SE / ARIETTA V70 SE / ARIETTA S70 SE *SE: Standard Edition
ARIETTA 70 LE / ARIETTA V70 LE / ARIETTA S70 LE
ARIETTA 70 LE+ / ARIETTA V70 LE+ / ARIETTA S70 LE+ *LE: Limited Edition

for Cardiology:

ARIETTA 70 CV / ARIETTA V70 CV / ARIETTA S70 CV *CV: Cardiovascular

for Surgery:

ARIETTA 70 SURGERY / ARIETTA V70 SURGERY / ARIETTA S70 SURGERY
ARIETTA 70 INTRAOPERATIVE / ARIETTA V70 INTRAOPERATIVE /
ARIETTA S70 INTRAOPERATIVE
ARIETTA 70 PE / ARIETTA V70 PE / ARIETTA S70 PE *PE: Premium Edition

for Primary Care:

ARIETTA 70 PC / ARIETTA V70 PC / ARIETTA S70 PC

for EUS:

ARIETTA 70 ENDOSCOPIC / ARIETTA V70 ENDOSCOPIC / ARIETTA S70 ENDOSCOPIC

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