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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:	***ALOKA ARIETTA 850 (*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/A1:2013, EN 60601-1-2:2007/AC:2010
EN 60601-2-37:2008, EN 62366:2008/A1:2015, EN 62304:2006:/AC:2008
EN 60601-1-6:2010/A1:2015, EN 1041:2008, EN ISO 14971:2012, 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.

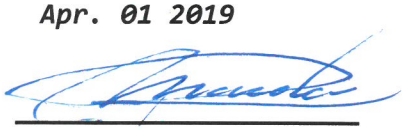
Standards : RoHS Directive Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product is

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: ***G3002593***

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 ALOKA ARIETTA 850.

This Declaration of Conformity is also effective to Marketing names of the following in addition to the original model. Below Tailoring variations(Marketing Name) are NOT mentioned in system label.

ARIETTA 850

ALOKA ARIETTA 850SE / ARIETTA 850SE

ALOKA ARIETTA 850PX / ARIETTA 850PX

ALOKA ARIETTA 850Endoscopic / ARIETTA 850Endoscopic

ALOKA ARIETTA 850Endoscopic PX / ARIETTA 850Endoscopic PX

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http://www.hitachi.com/businesses/healthcare/index.html