

## EC-DECLARATION OF CONFORMITY

Manufacturer: Hitachi, Ltd.  
Address: 2-16-1, Higashi-Ueno Taito-ku Tokyo, 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 65**

Classification (MDD, Annex IX): II a 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 : \*\*\*\*\* Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product are :  
EN 60601-1: 2012, EN 60601-1:2006/A1:2013, EN 60601-1-2: 2007  
EN 60601-2-37:2008, EN 62366: 2008/A1: 2015,  
EN 62304: 2006, EN 60601-1-6: 2010/A1: 2015, EN ISO 14971: 2012,  
EN ISO 15223-1: 2016, EN ISO 10993-1:2009, EN 1041:2008

Other Standards :  
EN 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. Tokyo Works**  
Address: **3-7-19 Imai, Ome-shi, Tokyo, 198-8577 Japan**

Starting of CE Marking: **20643188**

Date: **Oct 18, 2018**

Signature:



Name of issuer : Ryosuke Maeda

Place: **Tokyo, JAPAN**

Position : Management Representative