

## 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: **Transvaginal Electronic Convex Sector Scanner**  
Model Code REF : **ASU-1012**

Classification (MDD, Annex IX): Ila  
Categories (RoHS( II ), Annex I): No.8  
Classification rule (MDD, Annex IX): Rule 5

**Statement:**

We are exclusively responsible for the declaration of conformity and herewith declare that the above-mentioned product 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 as amended by 2007/47/EC;**

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.**

Production facility : **Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory**  
Address: **2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN**

Starting of CE Marking: G3052295  
Date: Nov. 11, 2019

Signature:



Name of issuer : Ryosuke Maeda  
Position : Management Representative

Place: Tokyo, JAPAN