

## 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: **S211 Probe**  
Model Code REF : **S211**

Classification (MDD, Annex IX): **Ila**  
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 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: **G3009964**  
Date: Jun.10, 2019

Signature:



Name of issuer : **Ryosuke Maeda**  
Position : **Management Representative**

Place: **Tokyo, JAPAN**