HITACHI
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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: **Convex Array Probe**
Model Code REF : EUP-C715

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 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: G3013168
Date: Jun.10,2019

Signature: 

Name of issuer : Ryosuke Maeda Place: ***Tokyo, JAPAN***
Position : Management Representative