HITACHI
Inspire the Next

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: **Biplane Transrectal / Vaginal Probe**
Model Code REF : EUP-CC531S

Classification (MDD, Annex IX): IIa
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: G3013827
Date: Sep.03,2019

Signature: 

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