

EC-DECLARATION OF CONFORMITY

Manufacturer: FUJIFILM Healthcare Corporation
Address: 2-1, Shintoyofuta, Kahiswa-shi, Chiba, 277-0804 JAPAN

Selected conformity assessment procedure:
MDD Annex II excluding (4) RoHS Article 7 (b), Module A

EU Authorized representative: **FUJIFILM Healthcare Deutschland GmbH**
Address: **Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany**

Product: **MXS1 Probe**
Model Code : **MXS1**

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. 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 Rheinland LGA Products GmbH is Notified Body with identification no. 0197**
Address (for MDD): **Tillystraße 2, 90431 Nürnberg, Germany**

RoHS Directive : **Directive 2011/65/EU of 8 June 2011 and (EU) 2015/863 of 31 March 2015 concerning on the restriction of the use of certain hazardous substances in electrical and electronic equipment.**

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

Start of CE Marking: **G3126322**
Date: **Jul. 01, 2021**

Signature:



Name of issuer : **Shinichi Chiba** Place: **Kashiwa, JAPAN**
Position : **Senior Manager, Quality Assurance Department**