FUJIFILM

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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: **S3ESL1 Probe**
Model Code : S3ESL1

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. 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: G3125959
Date: Jul. 01, 2021

Signature:

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