FUJIFILM

EU-DECLARATION OF CONFORMITY

Manufacturer: FUJIFILM Healthcare Corporation
Address: 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan
Actor ID/SRN: JP-MF-000018708

EU Authorized representative: **FUJIFILM Healthcare Deutschland GmbH**
Address: **Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany**
Actor ID/SRN: DE-AR-000017504

Statement:

We are exclusively responsible for the declaration of conformity and herewith declare that the below mentioned products including all its options meet the provisions of the following EU Regulation and EC Council Directives and common specifications. All supporting documentations are retained under the premises of the manufacturer.

Basic UDI-DI; 457359621US_SystemsWE
referred to in Part C of Annex VI

Product: ***Diagnostic Ultrasound System***

Model Code: ***ARIETTA 650*** *(*Include attachment sheet)*

Serial Number: G3171472

UMDNS Code:15-976 GMDN Code: 40761 EMDN Code: Z110401

Photograph for market plate:

Intended purpose :

It is intended to be used by qualified medical doctors and any qualified persons by national law for performing tomographic and hemodynamics diagnoses in the following parts of the human body:

Abdominal／Cardiac／Obstetrics／Gynecology／Superficial organs／Urology／Intraoperative

Classification／rule (MDR, Annex XIII): Ⅱa／Rule 10 Categories (RoHS(Ⅱ), Annex I): No.8

FUJIFILM

Regulation／Directive

General applicable Regulation／Directives:

Medical Device Regulation : (EU)/2017/745

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.

References CS; Non Common Specification, because it has not been issued yet.

Standards;

MDR Harmonized Standards (published in the Official Journal of the European Union) applicable to this product are :

No Harmonized Standards related to ARIETTA 650

Other Standards :

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 62304:2006

EN 60601-1-6:2010/A1:2015, EN 60601-2-37:2008/A1:2015, EN 62366:2008/A1:2015,

EN ISO 14971:2012, EN ISO 10993-1:2020, EN 1041:2008/A1:2013,
EN ISO 15223-1:2016, EN ISO 13485:2016/AC:2018

Standards : RoHS Directive Harmonized Standards (published in the Official Journal of the European Union) applicable to this product is :

EN IEC 63000:2018

Notified body :	TÜV Rheinland LGA Products GmbH is Notified Body with identification no. 0197
Address :	Tillystraße 2, 90431 Nürnberg, Germany
Selected conformity assessment procedure: (for MDR)	MDR : Annex **IX**
Certification Identification Number:	HZ 2251444-2
Selected conformity assessment procedure (for RoHS)	Article 7 (b), Module A

FUJIFILM

Additional Information;

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

Place: ***Chiba, JAPAN***

Date: ***JUN. 20, 2022***

Signature: Shinichiro Kishi

Name of issuer : Shinichiro Kishi
Position : Senior Manager
Product Design Department

Shinichi Chiba
Person responsible
for regulatory compliance

FUJIFILM

Attachment sheet for Declaration of Conformity of ARIETTA 650.

This Declaration of Conformity is also effective to following marketing name(s)[1].

ARIETTA 650 DeepInsight

1 “marketing name is NOT printed in the product label and we use it to our product specification and brochure depend on system configuration.