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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, 65205 Wiesbaden, Germany**
Actor ID/SRN: DE-AR-000017504

Statement:

We are exclusively responsible for the declaration of conformity and herewith declare that the above 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; 457359620X-ray_CTZU
referred to in Part C of Annex VI

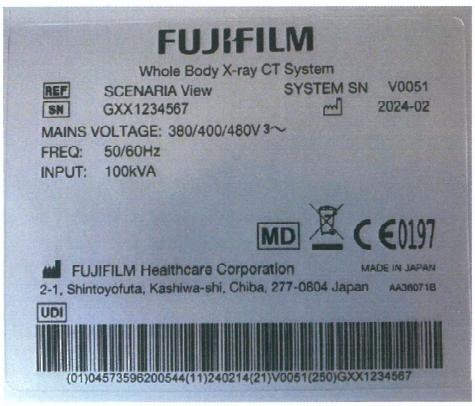
Product: ***Whole Body X-ray CT System***

Model Code: ***SCENARIA View***

Serial Number: V0051 or later

UMDNS Code:15-956 GMDN Code:37618 EMDN Code: Z110306

Photograph for market plate:



Intended purpose :

This system is intended to use at any part of the whole body to get computed tomography images and those images are used for diagnostic purposes.

Classification／rule (MDR, Annex XIII): II b／Rule 10 indent 5 Categories (RoHS(II), Annex I): No.8

Digitally signed by Botnaru Andrei
Date: 2024.06.12 11:04:26 EEST
Reason: MoldSign Signature
Location: Moldova

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Regulation／Directive

General applicable Regulation／Directives:

Medical Device Regulation : (EU)/2017/745

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.

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

Notified body : TÜV Rheinland LGA Product GmbH is Notified Body with identification no. 0197
Address (for MDR): Tillystraße 2, 90341 Nürnberg, Germany

Selected conformity assessment procedure: MDR : Annex **IX**

Certification Identification Number: HZ 2251444-1

Selected conformity assessment procedure (for RoHS): Article 7 (b), Module A

Additional Information;

Production facility : ***FUJIFILM Healthcare Manufacturing Corporation Medical System Operations Group,Kashiwa***
Address: ***2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN***
3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

Place: ***JAPAN***

Date: ***2024-02-14***

Signature:

Name of issuer : Kenji Sakakibara
Position : Deputy General Manager
MS R&D Department

Yuta Amano
Person responsible
for regulatory compliance

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Attachment1 for Declaration of Conformity of SCENARIA View.

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

SCENARIA View Focus Edition

[1] "marketing name" is not printed in the product label and we use it to our product specification and brochure depend on system configuration.

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Attachment2 for Declaration of Conformity of SCENARIA View.

Please refer to the following additional information on EC Declaration of Conformity.
This information is to be maintained with corresponding EC Declaration of Conformity.

Material Description applicable to
Declaration of Conformity：

Mat
Headrest 1
Sliding-type Immobilizing bands
Head band
Chin band
Phantom fixed base
External speaker
Water Phantom (165φ, 305φ, 230φ, 380φ:4set)
PE Phantom (230φ, 260φ, 350φ, 410φ: 4 set)
HF Armrest HF and Arm band
Leg mat
Triangular mat
Headrest 2
Foot switch (right and left : 1set)
Monitor
Keyboard
InterphoneBox
English Label
Italian Label
Spanish Label
French Label
German Label
System Software
MWM
ECG scan
Dual Energy Scan
Shuttle Scan
Spacer 1
Spacer 2
Chin rest
IV pole
Head band OP
Chin band OP
Armrest FF
Legrest tabletop
Wrist band
IHE/SWF&MPPS
Quality Exam
Water Phantom for Quality Exam
QA Phantom for Quality Exam
Injector Synchronization
Printed Circuit Board for Injector Synchronization
Software for Injector Synchronization
Wire cable for Nemoto Injector
Wire cable for Bayer / Imaxeon / Medrad Injector
CAN cable for Bayer / Medrad / Ulrich Injector
UPS
Stand Microphone
guideShot
guideShot parts for Gantry
Foot switch for guideShot
MCR
AutoPositioning
Camera for AutoPositioning