



EU Declaration of Conformity

We **EIZO Corporation**
153, Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan,

declare under our sole responsibility that the product:

Brand Name: **EIZO**
Kind of equipment: **LCD Monitor (Medical Device Equipment)**
Basic UDI-DI: **4995047MonitorVDUE2**
Type designation: **RadiForce RX250#**

(# represents any characters or blank)

Classification: **class I (MDR, Annex VIII, Section 6, Rule 13)**
Conformity assessment route: **MDR, Annex II + Annex III**

is in compliance with:

Harmonized Standards

Safety **EN60601-1:2006/A1:2013**
EMC **EN60601-1-2:2015(Group 1 Class B)**
RoHS **EN50581:2012**

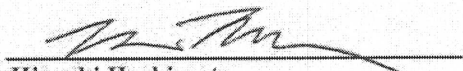
and following the provision of Regulations or Directives

(EU) 2017/745 : **MDR**
2011/65/EU : **RoHS**

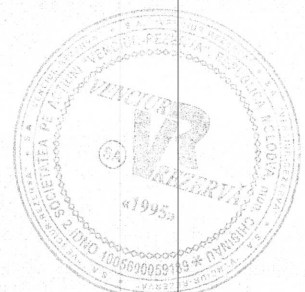
This Declaration of Conformity is valid from: **April 2021**

Manufacturer: **EIZO Corporation**
Place: **Hakusan, Ishikawa, Japan**
SRN (Single Registration Number): **Assigned after implementation of EUDAMED**
Date: **April 12, 2021**

Signature:


Hiroaki Hashimoto
Senior Manager,
Regulatory Compliance and Safety Division

Our Authorized Representative in the European Union for this product is
EIZO GmbH (SRN: Assigned after implementation of EUDAMED)
Carl-Benz-Straße 3, 76761 Rülzheim, Germany



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COPY



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

has established and applies a quality management system for medical devices
for the following scope:

In accordance with EN ISO 13485:2016 Medical devices
-Quality management systems-Requirements for regulatory
purposes (ISO 13485:2016)
See attachment(s) for the scope

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

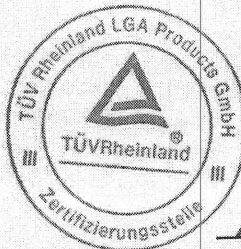
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-18
Certificate Registration No.: SX 60146170 0001
An audit was performed. Report No.: 12043441 005
This Certificate is valid until: 2022-09-30

Certification Body



Date 2020-01-18



Masahiro Asami

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146170 0001
Report No.: 12043441 005

Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

Design and Development, Manufacture, Distribution,
Installation and Service of Display monitor equipment and
Peripherals for Medical systems (OR, IVR, Diagnostic imaging
system and PACS)

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Certification Body



Date: 2020-01-18

M. Asami
Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146170 0001
Report No.: 12043441 005

Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

Site(s) included:
EIZO Corporation Headquarters
153 Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan

Scope:
Design and Development, Manufacture, Distribution,
Installation and Service of Display monitor equipment and
Peripherals for Medical systems (OR, IVR, Diagnostic imaging
system and PACS)

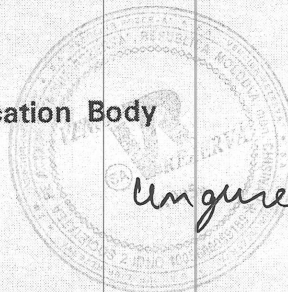
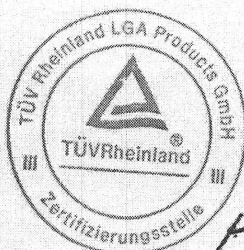
Eizo Corporation Tokyo Sales Office
Omori Bellport Bldg., E,6-22-7 Minamioi, Shinagawa, Tokyo
140-0013, Japan

Scope:
Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Ungureanu

Date: 2020-01-18

M. Asami
Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146170 0001
Report No.: 12043441 005

Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

Site(s) included:

EIZO Corporation Nagoya Sales Office
Nagoya Nishiki City Bldg., 1-6-5 Nishiki, Naka, Nagoya,
Aichi 460-0003, Japan

Scope:

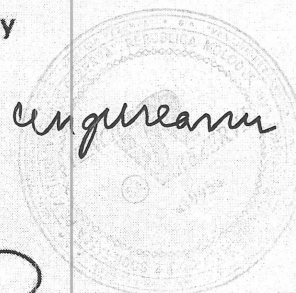
Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

EIZO Corporation Hokuriku Sales Office
153 Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan

Scope:

Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

Certification Body



Date: 2020-01-18


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60146170 0001
Report No.: 12043441 005

Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

Site(s) included:

EIZO Corporation Osaka Sales Office
Shin-Osaka Dai-ichi Seimei Bldg., 3-5-24 Miyahara, Yodogawa,
Osaka 532-0003, Japan

Scope:

Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

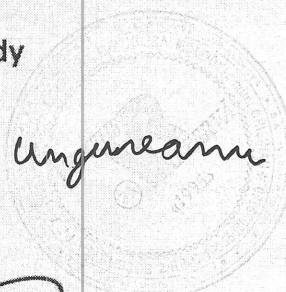
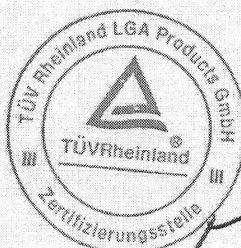
EIZO Corporation Fukuoka Sales Office

Fukuoka Fukuoka Seimei Bldg., 3-6-11 Watanabe-dori, Chuo,
Fukuoka 810-0004, Japan

Scope:

Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

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Date: 2020-01-18


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60146170 0001
Report No.: 12043441 005

Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

Site(s) included:

EIZO Corporation Sendai Sales Office
Sendai Dai-ichi Seimei Tower Bldg., 4-6-1 Ichiban, Aoba,
Sendai, Miyagi 980-0811, Japan

Scope:

Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

EIZO Corporation Hiroshima Sales Office
JEI Hiroshima Hatchobori Bldg., 14-4 Hatchobori, Naka,
Hiroshima 730-0013, Japan

Scope:

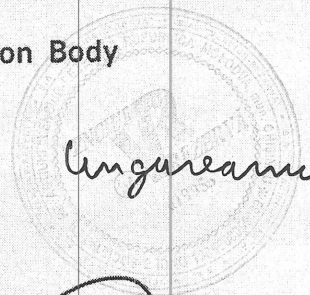
Distribution of Display monitor equipment and Peripherals
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Deutsche
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Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

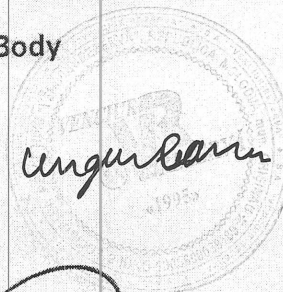
Site(s) included:
EIZO Corporation Sapporo Sales Office
Nippon Life Sapporo-kitaguchi Bldg., 4-12 Kita 7-jo nishi,
Kita, Sapporo, Hokkaido 060-0807, Japan

Scope:
Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

EIZO Corporation Takamatsu Sales Office
Crinum Bldg., 2062-4 Fuseishi, Takamatsu, Kagawa 761-8071,
Japan

Scope:
Distribution of Display monitor equipment and Peripherals
for Medical systems (OR, IVR, Diagnostic imaging system and
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Organization: EIZO Corporation
153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

Scope:

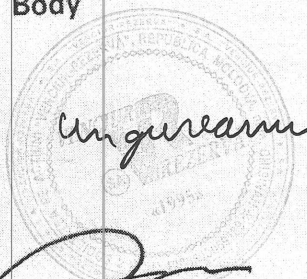
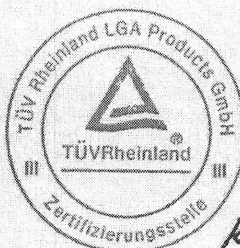
Site(s) included:
EIZO Support Network Corporation Headquarters
153 Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan

Scope:
Service of Display monitor equipment and Peripherals for
Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

EIZO Support Network Corporation EIZO Maintenance Center
153 Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan

Scope:
Service of Display monitor equipment and Peripherals for
Medical systems (OR, IVR, Diagnostic imaging system and
PACS)

Certification Body



Date: 2020-01-18

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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153 Shimokashiwano
Hakusan, Ishikawa
924-8566 Japan

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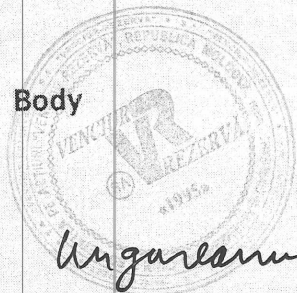
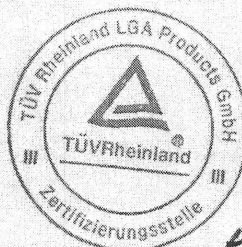
Site(s) included:
EIZO Support Network Corporation Field Support Sec.
Omori Bellport Bldg., E,6-22-7 Minamioi, Shinagawa, Tokyo
140-0013, Japan

Scope:
Installation and Service of Display monitor equipment and
Peripherals for Medical systems (OR, IVR, Diagnostic imaging
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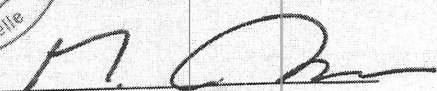
EIZO Support Network Corporation EIZO Support Tokyo
Omori Bellport Bldg., E,6-22-7 Minamioi, Shinagawa, Tokyo
140-0013, Japan

Scope:
Installation and Service of Display monitor equipment and
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Site(s) included:
EIZO Support Network Corporation EIZO Support Hokuriku
153 Shimokashiwano, Hakusan, Ishikawa 924-8566, Japan

Scope:
Installation and Service of Display monitor equipment and
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EIZO Support Network Corporation EIZO Support Takamatsu
Crinum Bldg., 2062-4 Fuseishi, Takamatsu, Kagawa 761-8071,
Japan

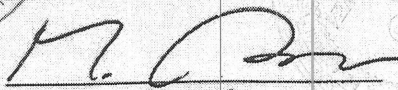
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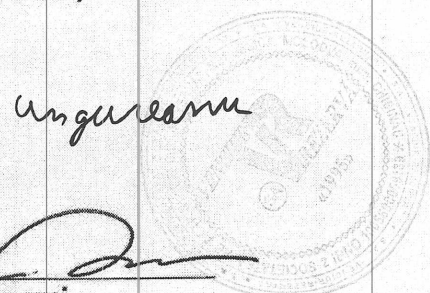
Site(s) included:
EIZO Support Network Corporation EIZO Support Hiroshima
JEI Hiroshima Hatchobori Bldg., 14-4 Hatchobori, Naka,
Hiroshima 730-0013, Japan

Scope:
Installation and Service of Display monitor equipment and
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EIZO Support Network Corporation EIZO Support Sapporo
Nippon Life Sapporo-kitaguchi Bldg., 4-12 Kita 7-jo nishi,
Kita, Sapporo, Hokkaido 060-0807, Japan

Scope:
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