

Certificate



Certificate no.

CU 72123111 01

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Manufacturing Plant:

Shimadzu Corporation
Medical Instruments Plant
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Test report no.: USA-JT 12311419 001

Client Reference: -

Tested to:

IEC 60601-1-3:2008
IEC 60601-2-54:2009
ANSI/AAMI ES60601-1:2005
CAN/CSA-C22.2 No. 60601-1-08
CAN/CSA-C22.2 NO. 60601-1-3-09
CAN/CSA-C22.2 NO. 60601-2-54:11

Certified Product: X-RAY TV SYSTEM

License Fee - Units

Model Designation: X-RAY TV SYSTEM SONIALVISION G4

7

Rated Voltage:

- 1) 3 AC 200/220/240V/380/400/415/440/480V; 50/60Hz
- 2) 1 AC 200/220/230/240V; 50/60Hz

Rated Power:

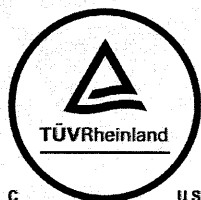
- 1) 133kVA
- 2) 7kVA

Protection Class: I, Type B applied part

7

Appendix: 1, 1-22

Licensed Test mark:



Signature

Dipl.-Ing. (FH) M. Geiser
QA Certification Officer

Date of Issue

(day/mo/yr)

27/12/2012

Certificate



Certificate no.

CU 72123111 02

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Manufacturing Plant:

Shimane Shimadzu Corp.
2698 Naoe, Hikawa-cho
IZUMO-SHI, SHIMANE 699-0631
JAPAN

Test report no.: USA-JT 12311419 001

Client Reference: -

Tested to: IEC 60601-1-3:2008
IEC 60601-2-54:2009
ANSI/AAMI ES60601-1:2005
CAN/CSA-C22.2 No. 60601-1-08
CAN/CSA-C22.2 NO. 60601-1-3-09
CAN/CSA-C22.2 NO. 60601-2-54:11

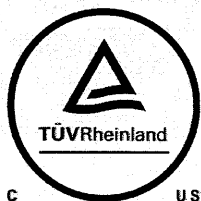
Certified Product: X-RAY TV SYSTEM

License Fee - Units

Additional Manufacturing Plant: see above

(K751205)

Licensed Test mark:



Signature

Date of Issue

(day/mo/yr)

27/12/2012

Bipl.-Ing. (FH) M. Geiser
QA Certification Officer

Shimadzu Corporation
Mr. Katsunori Nakata
Medical Equipment Quality Adm. Div.

Date: 13 September, 2013
Our ref.: 214039635
Your ref.: ZCBR-13A027A

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 6048511, Japan

Approval of modification for X-RAY TV SYSTEM

Type Designation : SONIALVISION G4
License No. : CU 72123111
Test Report No. : 12311419 002

Dear Mr. Katsunori Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 28, August, 2013.

Please find enclosed a copy of Notice of Alteration, authorised by us, stamped "Genehmigt/Approved" and dated 06, September, 2013.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Products
Medical Safety Testing



M. Oshiki
Project Engineer



C. Chiu
Senior Expert

Enclosure

Certificate



Certificate no.

CU 72141713 01

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Manufacturing Plant:

Shimadzu Corporation
Medical Instruments Plant
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Test report no.: USA-DS 12311419 003

Client Reference: Katsunori Nakata

Tested to:

ANSI/AAMI ES60601-1:2005+A2 (R2012)
IEC 60601-1-3:2008
IEC 60601-2-43:2010
IEC 60601-2-54:2009
CAN/CSA-C22.2 No. 60601-1-08 (R2013)
CAN/CSA-C22.2 NO. 60601-1-3-09
CAN/CSA-C22.2 NO. 60601-2-43:11
CAN/CSA-C22.2 NO. 60601-2-54:11

Certified Product: X-RAY TV SYSTEM

License Fee - Units

Model Designation: X-RAY TV SYSTEM SONIALVISION G4

7

Rated Voltage:

- 1) 3 AC 200/220/240V/380/400/415/440/480V, 50/60Hz
- 2) 1 AC 200/220/230/240V, 50/60Hz

Rated Power:

- 1) 133kVA
- 2) 7kVA

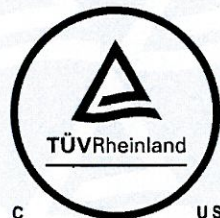
Protection Class: I, Type B applied part

Special Remarks: Replaces Certificate CU72123111.

7

Appendix: 1, 1-27

Licensed Test mark:



Date of Issue

(day/mo/yr)

01/07/2014

Certificate



Certificate no.

CU 72141713 02

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
NAKAGYO-KU, KYOTO 604-8511
JAPAN

Manufacturing Plant:

Shimane Shimadzu Corp.
2698 Naoe, Hikawa-cho
IZUMO-SHI, SHIMANE 699-0631
JAPAN

Test report no.: USA-DS 12311419 003

Client Reference: Katsunori Nakata

Tested to:

ANSI/AAMI ES60601-1:2005+A2 (R2012)
IEC 60601-1-3:2008
IEC 60601-2-43:2010
IEC 60601-2-54:2009
CAN/CSA-C22.2 No. 60601-1-08 (R2013)
CAN/CSA-C22.2 NO. 60601-1-3-09
CAN/CSA-C22.2 NO. 60601-2-43:11
CAN/CSA-C22.2 NO. 60601-2-54:11

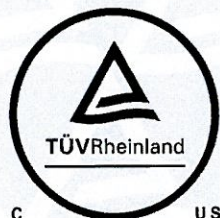
Certified Product: X-RAY TV SYSTEM

License Fee - Units

Additional Manufacturing Plant: see above

(K751205)

Licensed Test mark:



Date of Issue

(day/mo/yr)

01/07/2014

Shimadzu Corporation

Mr. Kazuhiko Tsutsui
Medical Systems Division
Quality Assurance Dept.
Regulatory Group

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 12 March, 2015
Our ref.: 214055095
Your ref.: ZCBR-14A053 (#2014-010)
ZCBR-14A054

Approval of modification for X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72141713
Test Report No. : 12311419 004

Dear Mr. Tsutsui,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2014-10-09.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2014-03-12.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

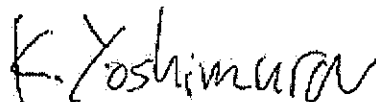
Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Kansai Technology Assessment Center
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Project Engineer



Kenji Yoshimura
Senior Expert

Enclosure

Shimadzu Corporation

Mr. Kazuhiko Tsutsui
Medical Systems Division
Quality Assurance Dept.
Regulatory Group

Date: 22 May, 2015
Our ref.: 214061718
Your ref.: ZCBR-15A013/014

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Approval of modification for CEILING TYPE X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72141713
Test Report No. : 12311419 005

Dear Mr. Tsutsui,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated Mar. 18, 2015.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2015-05-20.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Kansai Technology Assessment Center
Products
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Project Engineer

Shinji Onishi
Senior Project Engineer

Enclosure

TÜV Rheinland Japan Ltd.
Kansai Technology Assessment Center
1-3-14 Fukae Minami
Higashinari-ku
Osaka 537-0002, Japan

CSC : +81-6-6355-5400
Tel : +81-6-7656-6888
Fax : +81-6-7668-5777
e-mail: info@jpn.tuv.com
www.jpn.tuv.com

テュフ ラインランド ジャパン株式会社
関西テクノロジーセンター (KTAC)
〒537-0002
大阪市東成区深江南1-3-14

カスタマーサービスセンター: 06-6355-5400
Tel : 06-7656-6888
Fax : 06-7668-5777
e-mail: info@jpn.tuv.com
www.jpn.tuv.com

Shimadzu Corporation
Medical Systems Division

Date: 16 July, 2015
Our ref.: 214061718
Your ref.: ZCBR-15A014

Mr. Katsunori Nakata, Assistant Manager
Quality Assurance Dept.

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Approval of modification for X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72141713
Test Report No. : 12311419 006

Dear Mr. Nakata,

We hereby recognise the correction of description in IEC 60601-2-54:2009 clause 203.6.4.5:
from "Measured" to "Measured value and Calculation value".

Please find enclosed hardcopy of your e-mail, authorised by us, stamped
"Genehmigt/Approved" and dated 2015-07-10.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your
future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Project Engineer



Kenji Yoshimura
Team Leader of Medical Safety Testing

Enclosure

Shimadzu Corporation

Mr. Katsunori Nakata
Medical Systems Division
Quality Assurance Dept.

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 9 March, 2016
Our ref.: 214069554
Your ref.: ZCBR-15A090/091

Approval of modification for X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72141713
Test Report No. : 12311419 007

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2016.02.23.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2016-03-09.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Kansai Technology Assessment Center
Products
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Project Engineer



Shinji Onishi
Senior Project Engineer

Enclosure

Certificate



Certificate no.

CU 72182808 01

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-Ku, Kyoto
604-8511 Japan

Manufacturing Plant:

Shimadzu Corporation
Medical Instruments Plant
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 Japan

Test report no.: USA- 12311419 008

Client Reference: ZCBR-17A061

Tested to:

ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1
IEC 60601-1-3:2008+A1
IEC 60601-1-6:2010+A1
IEC 60601-2-54:2009+A1
IEC 62304:2006
CAN/CSA-C22.2 No. 60601-1:14
CAN/CSA-C22.2 NO. 60601-1-3-09 + A1
CAN/CSA-C22.2 NO. 60601-1-6:11 + A1
CAN/CSA-C22.2 No. 60601-2-54:11 + GI1 (R2016) + A1
CAN/CSA-CEI/IEC 62304:14

Certified Product: X-RAY TV SYSTEM

License Fee - Units

Model Designation: X-RAY TV SYSTEM SONIALVISION G4

7

Rated Voltage:

- 1) 3 AC 200/220/240/380/400/415/440/480V, 50/60Hz
- 2) 1 AC 200/220/230/240V, 50/60Hz

Rated Power: 1) 133kVA
2) 7kVA

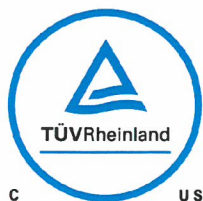
Protection Class: I, Type B applied part

Special Remarks: Replaces Certificate CU72141713

7

Appendix: 1, 1-54

Licensed Test mark:



Date of Issue
(day/mo/yr)

04/12/2018

Certificate



Certificate no.

CU 72182808 02

License Holder:

Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-Ku, Kyoto
604-8511 Japan

Manufacturing Plant:

Shimane Shimadzu Corp.
2698 Naoe, Hikawa-cho
Izumo-shi, Shimane
699-0631 Japan

Test report no.: USA- 12311419 008

Client Reference: ZCBR-17A061

Tested to:

ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1
IEC 60601-1-3:2008+A1
IEC 60601-1-6:2010+A1
IEC 60601-2-54:2009+A1
IEC 62304:2006
CAN/CSA-C22.2 No. 60601-1:14
CAN/CSA-C22.2 NO. 60601-1-3-09 + A1
CAN/CSA-C22.2 NO. 60601-1-6:11 + A1
CAN/CSA-C22.2 No. 60601-2-54:11 + GI1 (R2016) + A1
CAN/CSA-CEI/IEC 62304:14

Certified Product: X-RAY TV SYSTEM

License Fee - Units

Additional Manufacturing Plant: see above (K751205)

Licensed Test mark:



Date of Issue
(day/mo/yr)

04/12/2018

Shimadzu Corporation

Mr. Kazuhiko Tsutsui
Medical Equipment Quality Adm. Div.

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 10 May, 2019
Our ref.: 150107906
Your ref.: ZCBR-19A008/009

Approval of modification for X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72182808
Test Report No. : 12311419 009

Dear Mr. Tsutsui,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2019.4.12.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2019-05-10.

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV Rheinland Japan Ltd.
Kansai Technology Assessment Center
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Senior Project Engineer



Shinji Onishi
Senior Project Engineer

Enclosure

Shimadzu Corporation

Mr. Isao Nakata

Medical Systems Division
Quality Assurance Dept.
Regulatory Group

1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 13 April, 2020
Our ref.: 150119016
Your ref.: ZCBR-19A084/085

Approval of modification for X-RAY TV SYSTEM

Type Designation : X-RAY TV SYSTEM SONIALVISION G4
License No. : CU 72182808
Test Report No. : 12311419 010

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2020.02.27

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2020-04-10

Changes or additions to your existing certificate(s) are not necessary.

We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

Please feel free to contact us whatever your requirements may be.

With kind regards,

TÜV Rheinland Japan Ltd.
Kansai Technology Assessment Center
Products: Medical - Medical Safety Testing



Yasuaki Matsumoto
Senior Project Engineer



Shinji Onishi
Senior Project Engineer

Enclosure

TÜV Rheinland Japan Ltd.
Kansai Technology Assessment Center
1-3-14 Fukae Minami, Higashinari-ku, Osaka
537-0002, Japan

CSC : +81-6-6355-5400
Tel : +81-6-7656-6888
Fax : +81-6-7668-5777
e-mail : info@jpn.tuv.com
www.jpn.tuv.com

デュフラインランド ジャパン株式会社
関西テクノロジーセンター(KTAC)
〒537-0002 大阪市東成区深江南 1-3-14

カスタマーサービスセンター: 06-6355-5400
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Fax : 06-7668-5777
e-mail: info@jpn.tuv.com
www.jpn.tuv.com