

Certificate



Certificate no.

CU 72080391 01

License Holder:

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

Manufacturing Plant:

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

Test report no.: USA-DS 30890497 001

Client Reference: Nakata

Tested to: UL 60601-1:2003 R6.03
CAN/CSA-C22.2 No. 601.1-M90

Certified Product: Mobile X-Ray System

License Fee - Units

Model Designation: MOBILE X-RAY SYSTEM MobileDaTt Evolution
MOBILE X-RAY SYSTEM MobileArt Evolution

Rated Voltage: AC 100/110/120/200/220/230/240V, 50/60Hz
Rated Power: 1kVA
Protection Class: I

Appendix: 1, 1-4

Licensed Test mark:



Signature



Dipl.-Ing. R. Behrends
QA Certification Officer

Date of Issue
(day/mo/yr)

28/04/2008

Certificate



Certificate no.

CU 72080391 02

License Holder:

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

Manufacturing Plant:

Shimane Shimadzu Corporation
2698 Naoe-Machi, Hikawa-cho
HIKAWA-GUN, SHIMANE 699-0631
JAPAN

Test report no.: USA-DS 30890497 001

Client Reference: Nakata

Tested to: UL 60601-1:2003 R6.03
CAN/CSA-C22.2 No. 601.1-M90

Certified Product: Mobile X-Ray System

License Fee - Units

Additional Manufacturing Plant: see above

(K751205)

Licensed Test mark:



Signature

A handwritten signature in black ink, appearing to read 'R. Behrends'.

Dipl.-Ing. R. Behrends
QA Certification Officer

Date of Issue
(day/mo/yr)

28/04/2008

Product Safety and Quality
Electrical Services



Attn.: Mr. Nakata
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-Ku, Kyoto, 604-8511
JP

Greg Wheeler
gwheeler@us.tuv.com
02/05/2009

Alternate Construction / Additional Components

TUV File Number: 30890497.002
Type of Equipment: Mobile X-Ray System
Model Designation: Mobile X-Ray System MobileDaRt Evolution, Mobile
X-Ray System MobileArt Evolution

Dear Mr. Nakata:

We hereby approve your product modification as described below.

Addition of an alternate flat panel detector model CXDI-60G manufactured
by Canon.

Our approval of your product remains valid. Please keep this documentation
for reference purposes.

If we can be of any further assistance, please do not hesitate to call upon us.

Sincerely,
TUV Rheinland of North America, Inc.

A handwritten signature in cursive script that reads "Greg Wheeler".

Greg Wheeler

Encl. CDF (5 pages)

TUV Rheinland
of North America, Inc.
North American Headquarters

12 Commerce Road
Newtown, CT 06470

Tel: +1 (203) 426-0888
Fax: +1 (203) 426-4009
Mail: info@tuv.com
Web: www.tuv.com
Toll Free: +1 TUV-411-0042

Member of
TUV Rheinland Group

Certificate



Certificate no.

CU 72080391 03

License Holder:

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

Manufacturing Plant:

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

Test report no.: USA-DS 30890497 003

Client Reference: Nakata

Tested to: UL 60601-1:2003 R6.03
CAN/CSA-C22.2 No. 601.1-M90

Certified Product: Mobile X-Ray System

License Fee - Units

Change:

Model Designation: MOBILE X-RAY SYSTEM MobileDaRT Evolution
MOBILE X-RAY SYSTEM MobileArt Evolution
no longer valid

Addition:

Model Designation: Mobile X-Ray System MobileDaRT Evolution
Mobile X-Ray System MobileArt Evolution

Appendix: 1, 1-5

Licensed Test mark:



Signature



Dipl.-Ing. M. Glagla
QA Certification Officer

Date of Issue
(day/mo/yr)

20/04/2009

Shimadzu Corporation

Mr. Katsunori Nakata

Medical Equipment Quality Adm. Div.

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

Date: 15 September, 2009

Our ref.: 0213093640

Your ref.: ZCBR-09A151

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution

License No. : CU 72080391

Test Report No. : 30890497.004

Dear Mr. Katsunori Nakata,

We herewith recognise the modifications for your certified products as requested in your letter of 23.07.2009.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 15.09.2009.

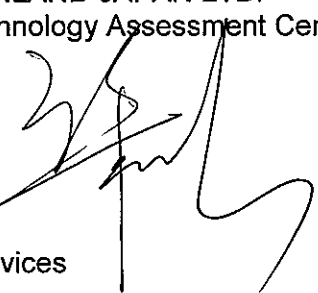
We appreciate your support and would like to offer our assistance in the approval of your future products through our extensive range of technical services.

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

With kind regards,

TÜV RHEINLAND JAPAN LTD.
Global Technology Assessment Center
Products

Jack Liang
Engineer
Medical Devices



Matthew Strege
Manager
Medical Devices

Enclosure

Shimadzu Corporation

Mr. Katsunori Nakata

Medical Equipment Quality Adm. Div.

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

Date: 18 November, 2010

Our ref.: 0214003855

Your ref.: ZCBR-10A187

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution,
Mobile X-ray System MobileArt Evolution

License No. : CU 72080391

Test Report No. : 30890497 005

Dear Mr. Nakata,

We herewith recognise the modifications for your certified products as requested in your letter of 03.09.2010.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 15.11.2010.

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

Vasily Kalakutskiy
Manager
Medical Devices
Regional Office West Japan



Carol Chiu
Project Engineer
Medical Devices

Enclosure

TÜV Rheinland Japan Ltd.

Regional Office West Japan

Wakasugi Center Bldg. Honkan 16F
2-9-1, Higashi-Tenma, Kita-ku
Osaka 530-0044, Japan

Tel : +81-6-6355-5777

Fax : +81-6-6354-8636

www.jpn.tuv.com

テュフ ラインランド ジャパン株式会社

西日本地域担当オフィス

〒530-0044 大阪市北区東天満2-9-1
若杉センタービル本館 16階

Tel : 06-6355-5777

Fax : 06-6354-8636

e-mail : info@jpn.tuv.com

Shimadzu Corporation

Mr. Katsunori Nakata

Medical Equipment Quality Adm. Div.

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

Date: 1 March, 2012

Our ref.: 0214021394

Your ref.: -

Approval of modification for Mobile X-ray System [UMDNS Code]

Type Designation : Mobile X-ray System MobileDaRt Evolution,
Mobile X-ray System MobileArt Evolution

License No. : CU 72080391

Test Report No. : 30890497 006

Dear Mr. Nakata,

We herewith recognise the modifications for your certified products as requested on 24.02.2012.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 29.02.2012.

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.

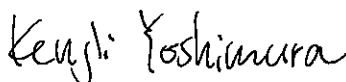
With kind regards,

TÜV RHEINLAND JAPAN LTD.

Products

Regional Office West Japan

Medical Devices



Kenji Yoshimura
Senior Expert



Carol Chiu
Senior Expert

Enclosure

TÜV Rheinland Japan Ltd.

Regional Office West Japan

Wakasugi Center Bldg. Honkan 16F

2-9-1, Higashi-Tenma, Kita-ku

Osaka 530-0044, Japan

Tel : +81-6-6355-5777

Fax : +81-6-6354-8636

www.jpn.tuv.com

テュフ ラインランド ジャパン株式会社

西日本地域担当オフィス

〒530-0044 大阪市北区東天満2-9-1

若杉センタービル本館 16階

Tel : 06-6355-5777

Fax : 06-6354-8636

e-mail : info@jpn.tuv.com

Certificate



Certificate no.

CU 72080391 04

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-MG 30890497 007

Client Reference: ZCBR-12A221

Tested to: UL 60601-1:2003 R6.03
CAN/CSA-C22.2 NO. 601.1-M90

Certified Product: Mobile X-Ray System

License Fee - Units

Addition:

Model Designation: Mobile X-ray System FDR Go

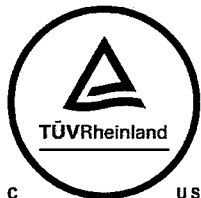
Change:

Manufacturing Plant: Shimane Shimadzu Corporation (K751205)
2698 Naoe-Machi, Hikawa-cho
HIKAWA-GUN, SHIMANE 699-0631 JAPAN

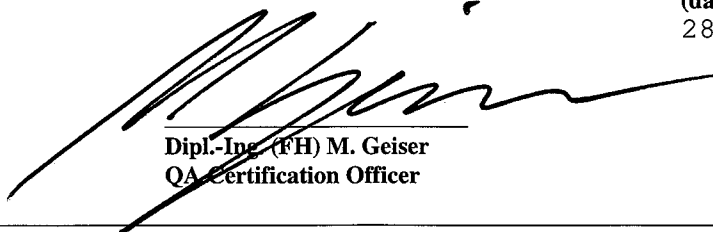
changed to : see above

Appendix: 1, 1-7

Licensed Test mark:



Signature



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

Date of Issue
(day/mo/yr)

28/12/2012

Shimadzu Corporation

Mr. Katsunori Nakata
Medical Systems Division

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

Date: 29 November, 2013
Our ref.: 214039653
Your ref.: ZCBR-13A006A

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution
Mobile X-ray System FDR Go

License No. : CU 72080391
Test Report No. : 30890497 008

Dear Mr. Katsunori Nakata

We hereby recognise the modification for your certified products as requested in your Notice of Alteration dated 11 April, 2013.

Please find enclosed a copy of your Notice of Alteration, authorised by us, stamped "Genehmigt/Approved" and dated 28 November, 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


M. Oshiki
Project Engineer

Enclosure


C. Chiu
Senior Expert

Certificate



Certificate no.

CU 72080391 05

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-30890497 009

Client Reference: ZCBR-12A221

Tested to:

UL 60601-1:2003 R6.03
IEC 60601-1-3:1994
IEC 60601-1-4:1996+A1
IEC 60601-2-7:1998
IEC 60601-2-28:1993
IEC 60601-2-32:1994
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
ANSI/AAMI ES60601-1:2005+A2
IEC 60601-1-3:2008
IEC 60601-2-54:2009

Certified Product: Mobile X-Ray System

License Fee - Units

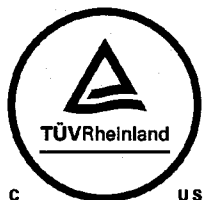
Addition

Test Requirement: IEC 60601-1-3:1994, IEC 60601-1-4:1996+A1,
IEC 60601-2-7:1998, IEC 60601-2-28:1993,
IEC 60601-2-32:1994,
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,
ANSI/AAMI ES60601-1:2005+A2,
IEC 60601-1-3:2008, IEC 60601-2-54:2009

Change

Test Requirement: CAN/CSA-C22.2 NO. 601.1-M90
withdrawn
Appendix: 1, 1-8

Licensed Test mark:



Date of Issue

(day/mo/yr)
20/12/2013

Certificate



Certificate no.

CU 72080391 06

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- 30890497 010

Client Reference: Katsunori Nakata

Tested to:

UL 60601-1:2003 R4.06
IEC 60601-2-7:1998
IEC 60601-2-28:1993
IEC 60601-2-32:1994
IEC 60601-1-3:1994
IEC 60601-1-4:1996+A1
CAN/CSA-C22.2 No. 60601-1-08
CAN/CSA-C22.2 NO. 60601-2-54:11
CAN/CSA-C22.2 NO. 60601-1-3-09
ANSI/AAMI ES60601-1:2005+A2
IEC 60601-2-54:2009
IEC 60601-1-3:2008

Certified Product: Mobile X-Ray System

License Fee - Units

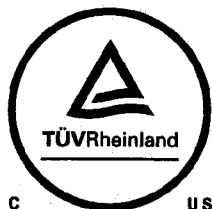
Changes

Test Requirement : UL 60601-1:2003 R6.03
changed to : see above

Model Designation: Mobile X-ray System FDR Go
withdrawn

Appendix: 1, 1-9

Licensed Test mark:



Date of Issue

(day/mo/yr)

14/01/2015

Shimadzu Corporation

Mr. Kazuhiko Tsutsui
Medical Equipment Quality Adm. Div.

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

Date: 23 April, 2015
Our ref.: 214057108
Your ref.: ZCBR-14A073B

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution
License No. : CU 72080391
Test Report No. : 30890497 011

Dear Mr. Tsutsui,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated Feb. 19, 2015.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2015-04-23.

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.

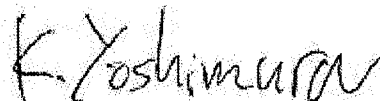
Please feel free to contact us whatever your requirements may be.

With kind regards,

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



Yasuaki Matsumoto
Project Engineer



Kenji Yoshimura
Senior Expert

Enclosure

Shimadzu Corporation

Mr. Katsunori Nakata
Medical Equipment Quality Adm. Div.

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

Date: 18 March, 2016
Our ref.: 214067083
Your ref.: ZCBR-15A070/071

Approval of modification for Mobile X-ray System

Type Designation : 1) Mobile X-ray System MobileArt Evolution
2) Mobile X-ray System MobileDaRt Evolution
License No. : CU 72080391
Test Report No. : 30890497 012

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated Jan. 29, 2016.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2016-03-18.

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



Shinji Onishi
Senior Project Engineer

Enclosure

Certificate



Certificate no.

CU 72172772 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-30890497 013

Client Reference: ZCBR-17A005/006A

Tested to:

ANSI/AAMI ES60601-1:2005+A2
IEC 60601-1-3:2008
IEC 60601-2-54:2009
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: Mobile X-Ray System

License Fee - Units

Model Designation: Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution

Rated Voltage: AC 100/110/120/200/220/230/240V, 50/60Hz
Rated Power: 1kVA
Protection Class: I

Special Remarks: Replaces Certificate CU72080391.

Appendix: 1, 1-23

Licensed Test mark:



Date of Issue

(day/mo/yr)
16/11/2017

Certificate



Certificate no.

CU 72172772 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- 30890497 013

Client Reference: ZCBR-17A005/006A

Tested to:

ANSI/AAMI ES60601-1:2005+A2
IEC 60601-1-3:2008
IEC 60601-2-54:2009
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: Mobile X-Ray System

License Fee - Units

Addition:

Additional Manufacturing Plant: see above

(K751205)

Licensed Test mark:



Date of Issue

(day/mo/yr)
16/11/2017

Shimadzu Corporation

Mr. Kazuhiko Tsutsui

Medical Equipment Quality Adm. Div.

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

Date: 24 May, 2018

Our ref.: 214098822

Your ref.: ZCBR-18A001/002

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution
License No. : CU 72172772
Test Report No. : 30890497 014

Dear Mr. Tsutsui,

We hereby recognize the modifications for your certified products as requested in your Notice of Alteration dated 2018.5.21.

Please find enclosed a copy of notice of Alterations/modification, authorized by us, stamped "Genehmigt/Approved" and dated 2018-05-24.

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

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

Mr. Isao Nakata
Medical Systems Division
Quality Assurance Dept.
Regulatory Group

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

Date: 26 September, 2019
Our ref.: 150113302
Your ref.: ZCBR-19A031

Approval of modification for Mobile X-ray System

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution

License No. : CU 72172772
Test Report No. : 30890497 015

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2019.04.24.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2019-09-26.

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



Shinji Onishi
Senior Project Engineer

Enclosure