

Zertifikat Certificate



Zertifikat Nr. Certificate No.
I 50153479

Blatt Page
0001

Ihr Zeichen Client Reference
ZCBR-08A314

Unser Zeichen Our Reference
ZO-DAB- 12016989 004

Ausstellungsdatum
30.01.2012

Date of Issue
(day/mo/yr)

Genehmigungsinhaber License Holder
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

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

Prüfzeichen Test Mark



Geprüft nach Tested acc. to

EN 60601-1:1990+A1+A2
EN 60601-1-3:1994
EN 60601-1-4:1996+A1
EN 60601-2-7:1998
EN 60601-2-28:1993
EN 60601-2-32:1994

Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

Röntgeneinrichtung Mobile X-ray System

UMDNS Code 13-272

Bezeichnungen : Mobile X-ray System MobileDaT Evolution	6
(Type Designations) Mobile X-ray System MobileArt Evolution	1
Nennspannung (Rated Voltage): AC 100/110/120/200/220/230/240V	
Nennfrequenz (Rated Frequency): 50/60Hz	
Nennleistung (Rated Power): 1kVA	
Klassifikationen: Schutzklasse I, Typ B	
MDD-Klasse IIb, Regel 10	
(Classifications: Protection Class I, Type B	
MDD Class IIb, rule 10)	

Hinweis: Neuerstellung von I 50127853 wegen Änderung der Bezeichnungen.

(Remark: Reissue of I 50127853, due to change of Type Designations.)

ANLAGE (Appendix): 1.1

Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.



Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: (+49/221)8 06 - 13 71 e-mail: cert-validity@de.tuv.com
Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

Dipl.-Ing. J. Taylor

Zertifikat Certificate



Zertifikat Nr. Certificate No.
I 50153479

Blatt Page
0002

Ihr Zeichen Client Reference
ZCBR-08A314

Unser Zeichen Our Reference
ZO-DAB- 12016989 004

Ausstellungsdatum
30.01.2012

Date of Issue
(day/month/year)

Genehmigungsinhaber License Holder
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

Fertigungsstätte Manufacturing Plant
Shimane Shimadzu Corporation
2698 Naoe-machi, Hikawa-cho
Hikawa-gun, Shimane
699-0631 JAPAN

Prüfzeichen Test Mark



Geprüft nach Tested acc. to

EN 60601-1:1990+A1+A2
EN 60601-1-3:1994
EN 60601-1-4:1996+A1
EN 60601-2-7:1998
EN 60601-2-28:1993
EN 60601-2-32:1994

Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

Röntgeneinrichtung Mobile X-ray System

wie Blatt 0001 (as page 0001)

UMDNS Code 13-272

Ergänzung (Addition)

Fertigungsstätte : (siehe oben)
(Factory) (see above)



Zertifizierungsstelle

Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: (+49/221)8 06 - 13 71 e-mail: cert-validity@de.tuv.com
Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

Dipl.-Ing. J. Taylor

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: 13-272]

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

License No. : I 50153479

Test Report No. : 12016989 005

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

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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

Zertifikat Certificate



Zertifikat Nr. Certificate No.
I 50153479

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0003

Ihr Zeichen Client Reference
K.N.

Unser Zeichen Our Reference
ZO-YAM- 12016989 006

Ausstellungsdatum
06.02.2013

Date of Issue
(day/mo/yr)

Genehmigungsinhaber License Holder
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

Fertigungsstätte Manufacturing Plant
Shimane Shimadzu Corp.
2698 Naoe, Hikawa-cho
Izumo-shi, Shimane
699-0631 JAPAN

Prüfzeichen Test Mark



Geprüft nach Tested acc. to

EN 60601-1:2006
EN 60601-1-3:2008
EN 60601-2-54:2009

Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

X-Ray Equipment Mobile X-ray System, as page 0001

UMDNS Code 13-272

Änderungen (Changes)

Prüfgrundlagen : EN 60601-1:1990+A1+A2

(Test Requirements) EN 60601-1-3:1994

ändern sich in : EN 60601-1:2006

(changed to) EN 60601-1-3:2008

Prüfgrundlagen : EN 60601-1-4:1996+A1, EN 60601-2-7:1998

(Test Requirements) EN 60601-2-28:1993, EN 60601-2-32:1994

entfallen (withdrawn)

Adresse der

Fertigungsstätte : Shimane Shimadzu Corporation

(Address of Factory) 2698 Naoe-machi, Hikawa-cho

Hikawa-gun, Shimane 699-0631 JAPAN

ändert sich in (changed to) : (siehe oben) (see above)

Ergänzung (Addition)

Prüfgrundlage (Test Requirement) : EN 60601-2-54:2009

ANLAGE (Appendix): 1.1

Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.



Zertifizierungsstelle

Dipl.-Ing. (FH) J. Taylor

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: (+49/221)8 06 - 13 71 e-mail: cert-validity@de.tuv.com

Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

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-13A006B

Approval of modification for Mobile X-ray System [UMDNS Code: 13-272]

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

License No. : I 50153479
Test Report No. : 12016989 007

Dear Mr. Katsunori Nakata

We hereby recognise the modification for your certified products as requested in your Notice of Alteration dated 21 June, 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



C. Chiu
Senior Expert

Enclosure

Zertifikat Certificate



Zertifikat Nr. *Certificate No.*
I 50153479

Blatt *Page*
0004

Ihr Zeichen *Client Reference*
ZCBR-12A221

Unser Zeichen *Our Reference*
ZO-OSH- 12016989 008

Ausstellungsdatum
09.12.2013

Date of Issue
(day/mo/yr)

Genehmigungsinhaber *License Holder*
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

Fertigungsstätte *Manufacturing Plant*
Shimadzu Corporation
Medical Instruments Plant
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

Prüfzeichen *Test Mark*



Geprüft nach *Tested acc. to*

EN 60601-1:2006+A11
EN 60601-1-3:2008
EN 60601-2-54:2009

Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

X-Ray Equipment Mobile X-ray System, wie Blatt 0001 (as page 0001)

UMDNS Code 13-272

Änderung (Change)

Prüfgrundlage: EN 60601-1:2006
(Test Requirement)
ändert sich in: EN 60601-1:2006+A11
(changed to)

ANLAGE (Appendix): 1.2



Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.

Zertifizierungsstelle

Carol Chiu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: (+49/221)8 06 - 13 71 e-mail: cert-validity@de.tuv.com
Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

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

Date: 8 September, 2014
Our ref.: 214049445
Your ref.: ZCBR-14A015
(#2014-003)

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

**Approval of modification for Mobile X-ray System
[UMDNS Code 13-272 (Radiographic Units, Mobile)]**

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution
License No. : I 50153479
Test Report No. : 12016989 009

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated May 16, 2014.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2014-08-18.

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.
Regional Office West Japan
Products
Medical
Medical Safety Testing


Izumi Yamamoto
Coordinator


Yasuaki Matsumoto
Project Engineer

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

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www.jpn.tuv.com

Zertifikat

Certificate



Zertifikat Nr. Certificate No.
I 50153479

Blatt Page
0005

Ihr Zeichen Client Reference
ZCBR-14A073B

Unser Zeichen Our Reference
ZOL-YAM- 12016989 010

Ausstellungsdatum
23.04.2015

Date of Issue
(day/mo/yr)

Genehmigungsinhaber License Holder
Shimadzu Corporation
1 Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 JAPAN

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

Prüfzeichen Test Mark



Safety
Regular
Production
Surveillance

www.tuv.com
ID 6000000000

Geprüft nach Tested acc. to

EN 60601-1:2006+A11+A12
EN 60601-1-3:2008
EN 60601-2-54:2009

Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

X-Ray Equipment Mobile X-ray System, wie Blatt 0001 (as page 0001)

UMDNS Code 13-272

Änderung (Change)

Prüfgrundlage: EN 60601-1:2006+A11
(Test Requirement)
ändert sich in: EN 60601-1:2006+A11+A12
(changed to)



ANLAGE (Appendix): 1.3

Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.

Zertifizierungsstelle

Tatsuhiko Nakada

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: (+49/221)8 06 - 13 71 e-mail: cert-validity@de.tuv.com
Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

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

Date: 26 February, 2016
Our ref.: 214067083
Your ref.: ZCBR-15A070/071

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

**Approval of modification for Mobile X-ray System
[UMDNS Code 13-272]**

Type Designation : 1) Mobile X-ray System MobileArt Evolution
2) Mobile X-ray System MobileDaRt Evolution
License No. : I 50153479
Test Report No. : 12016989 011

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 2016-02-24.

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


Izumi Yamamoto
Coordinator


Yasuaki Matsumoto
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
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www.jpn.tuv.com

Shimadzu Corporation

Mr. Katsunori Nakata

Medical Systems Division

Quality Assurance Dept., Regulatory Gr.

1 Nishinokyo-Kuwabara-cho

Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 13 November, 2017

Our ref.: 214083326

Your ref.: ZCBR-17A005/006

Approval of modification for Mobile X-ray System [UMDNS Code: 13-272]

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

License No. : I 50153479

Test Report No. : 12016989 012

Dear Mr. Nakata,

We hereby recognize the modifications for your certified products as requested in your Notice of Alteration dated 2017.7.24.

Please find enclosed a copy of notice of Alterations/modification, authorized by us, stamped "Genehmigt/Approved" and dated 2017-11-13.

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


Izumi Yamamoto
Coordinator


Yasuaki Matsumoto
Senior Project Engineer

Enclosure

TÜV Rheinland Japan Ltd.

Kansai Technology Assessment Center

1-3-14 Fukae Minami

Higashinari-ku

Osaka 537-0002, Japan

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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

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Tel : 06-7656-6888

Fax : 06-7668-5777

e-mail: info@jpn.tuv.com

www.jpn.tuv.com

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 [UMDNS Code: 13-272]

Type Designation : Mobile X-ray System MobileDaRt Evolution
Mobile X-ray System MobileArt Evolution
License No. : I 50153479
Test Report No. : 12016989 013

Dear Mr. Nakata,

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



Izumi Yamamoto
Coordinator



Yasuaki Matsumoto
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: 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. : I 50153479
Test Report No. : 12016989 014

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2019.4.24.

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

TÜV Rheinland Japan Ltd.
Kansai Technology Assessment Center
1-3-14 Fukae Minami
Higashinari-ku
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デュフ ラインランド ジャパン株式会社
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〒537-0002
大阪市東成区深江南1-3-14

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