

Zertifikat

Certificate



Zertifikat Nr. *Certificate No.*
I 50104654

Blatt *Page*
0001

Ihr Zeichen *Client Reference*

-

Unser Zeichen *Our Reference*

ZJL-CCH- 12014969 001

Ausstellungsdatum

26.04.2007

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 Corp.
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+A13
EN 60601-1-1:2001
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 Digital Radiography System

UMDNS Code 18-430

Bezeichnung: Digital Radiography System RADspeed safire
(Type Designation)

6

Nennspannung: (1) 3N 200/220/240/380/400/415/440/480V
(Rated Voltage) (2) 1N 200/220/230/240V

Nennfrequenz: 50/60Hz
(Rated Frequency)

Nennleistung: (1) 120kVA (2) 14.9kVA
(Rated Power)

Klassifikationen: Schutzklasse I, Typ B
MDD-Klasse IIb, Regel 10
(Classifications: Protection Class I, Type B
MDD Class IIb, rule 10)

Hinweis : Ersetzt I 50104654 Blatt 0001 vom 20.04.2007.

(Remark : Replaces I 50104654 page 0001, dated 20.04.2007.)

6

ANLAGE (Appendix): 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 Product Safety GmbH, Am Grauen Stein, D-51105 Köln

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. W. Herlitschke

Zertifikat Certificate



Zertifikat Nr. Certificate No.
I 50104654

Blatt Page
0002

Ihr Zeichen Client Reference
ZCBR-07A255

Unser Zeichen Our Reference
ZJL-CCH- 12014969 002

Ausstellungsdatum
27.06.2008

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

Prüfzeichen Test Mark



Geprüft nach Tested acc. to

EN 60601-1:1990+A1+A2+A13
EN 60601-1-1:2001
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 Digital Radiography System

UMDNS Code 18-430

Ergänzung (Addition)

Geräteidentifikation: GENERAL RADIOGRAPHY SYSTEM
(Product Identification)

Bezeichnung: GENERAL RADIOGRAPHY SYSTEM RADspeed Pro
(Type Designation)

Nennspannung: (1) 3N 200/220/240/380/400/415/440/480V

(Rated Voltage) (2) 1N 200/220/230/240V

Nennleistung: (1) 120kVA

(Rated Power) (2) 8.5kVA

Änderung (Change)

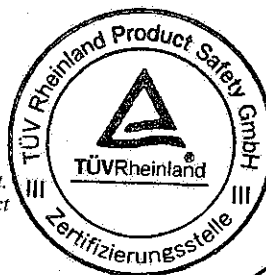
Name der Fertigungsstaette : Shimadzu Corporation
(Name of Factory) Medical Instruments Plant

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

1

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 Product Safety GmbH, Am Grauen Stein, D-51105 Köln
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. M. Geiser

Shimadzu Corporation
Quality Assurance Department
Medical Systems Division

Mr. Katsunori Nakata
Assistant Manager

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

Date: 24 June, 2011
Our ref.: 213090031/213093637
214008784
Your ref.: ZCBR-09A048A
ZCBR-09A147A
ZCBR-10A267

Approval of modification for Digital Radiography System [UMDNS Code 18-430]

Type Designation : Digital Radiography System RADspeed safire
Digital Radiography System RADspeed Pro
License No. : I 50104654
Test Report No. : 12014969 003

Dear Mr. Nakata,

We herewith recognise the modifications for your certified products as requested in your letter of 11.01.2011.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 14.06.2011.

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,

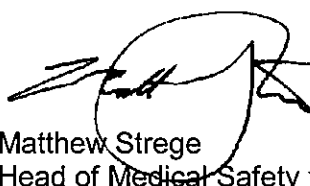
TÜV RHEINLAND JAPAN LTD.
Resional Office West Japan
Products
Medical Devices

Dmitry Abramov
Project Engineer



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



Matthew Strege
Head of Medical Safety testing

デュフ 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 50279308

Blatt Page
0001

Ihr Zeichen Client Reference
K.N.

Unser Zeichen Our Reference
ZO-YKE- 12311991 001

Ausstellungsdatum
07.04.2014

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 Digital Radiography System

UMDNS Code 18-430

Bezeichnung: Digital Radiography System RADspeed Pro
(Type Designation)

6

Nennspannung: (1) 3AC 200/220/240/380/400/415/440/480V
(Rated Voltage) (2) AC 200/220/230/240V

Nennfrequenz: 50/60Hz
(Rated Frequency)

Nennleistung: (1) 120kVA (2) 8.5kVA
(Rated Power)

Klassifikationen: Schutzklasse I, Typ B
MDD-Klasse IIb, Regel 10

(Classifications: Protection Class I, Type B
MDD Class IIb, rule 10)

ANLAGE (Appendix): 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

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

Zertifikat Certificate



Zertifikat Nr. Certificate No.
I 50279308

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0002

Ihr Zeichen Client Reference
K.N.

Unser Zeichen Our Reference
ZO-YKE- 12311991 001

Ausstellungsdatum
07.04.2014

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 Corp.
2698 Naoe, Hikawa-cho
Izumo-shi, Shimane
699-0631 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 Digital Radiography System, wie Blatt 0001 (as page 0001)

UMDNS Code 18-430

Ergänzung (Addition)

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

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

Carol Chiu

Shimadzu Corporation
Mr.Nakata

1 Nishinokyo-Kuwabara-cho
Nagagyo-ku, Kyoto
604-8511 JAPAN

Date: 7 August, 2014
Our ref.: 214048713
Your ref.: ZCBR-14A003A
ZCBR-13A010A

Approval of modification for Digital Radiography System [UMDNS Code 18-430]

Type Designation : Digital Radiography System RADspeed Pro
License No. : I 50279308
Test Report No. : 12311991 002

Dear Mr. Nakata,

We hereby recognise the modification for your certified products as requested in your Notice of Alteration dated 31 March, 2014 and 9 May, 2013.

Please find enclosed a copy of your Notice of Alteration, authorised by us, stamped "Genehmigt/Approved" and dated 7 August, 2014.

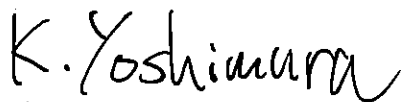
Changes or additions to your existing certificate(s) are not necessary.

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



K. Yoshimura
Team Leader

Enclosure



T.Nakada
Project Engineer

Shimadzu Corporation

Mr. K. Nakata
Medical Systems Division

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

Date : 19 December, 2014
Our ref. : 214051404
Your ref.: #2014-005-01

Approval of modification for Digital Radiography System [UMDNS Code 18-430]

Type designation(s) : Digital Radiography System RADspeed Pro
Report No. : 12311991 003
Certificate Number : I 50279308

Dear Mr. Nakata,

We herewith recognise the modifications for your certified products as requested in your Notice of Alterations dated 2014-12-04.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2014-12-19.

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


Izumi Yamamoto
Coordinator


Yasuaki Matsumoto
Project Engineer

Enclosure

Zertifikat

Certificate



Zertifikat Nr. *Certificate No.*
I 50279308

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0003

Ihr Zeichen <i>Client Reference</i>	Unser Zeichen <i>Our Reference</i>	Ausstellungsdatum	<i>Date of Issue</i> (day/mo/yr)
ZCBR-15A040/041	ZOL-YAM- 12311991 004	18.12.2015	

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+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 Digital Radiography System, wie Blatt 0001 (as page 0001)

UMDNS Code 18-430

Ergänzung (Addition)

Bezeichnung : General Radiography System RADspeed Pro
(Type Designation)

1

Änderung (Change)

Prüfgrundlage: EN 60601-1:2006+A11
(Test Requirement)

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



1

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

K. Yoshimura

Kenji Yoshimura

Shimadzu Corporation

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

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

Date: 8 July, 2016
Our ref.: 214073442
Your ref.: ZCBR-16A008/009

Approval of modification for Digital Radiography System [18-430]

Type Designation : Digital Radiography System RADspeed Pro
General Radiography System RADspeed Pro

License No. : I 50279308
Test Report No. : 12311991 005

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2016.05.19.

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2016-07-08.

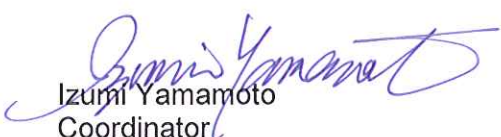
Changes or additions to your existing certificate(s) are not necessary.

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



Izumi Yamamoto
Coordinator



Kazuhiro Yoshida
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

CSC : +81-6-6355-5400
Tel : +81-6-6355-5777
Fax : +81-6-6354-8636
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
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

カスタマーサービスセンター: 06-6355-5400
Tel : 06-6355-5777
Fax : 06-6354-8636
e-mail: info@jpn.tuv.com
www.jpn.tuv.com

Zertifikat

Certificate



Zertifikat Nr. *Certificate No.*
I 50279308

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0004

Ihr Zeichen *Client Reference*
2017-TU019

Unser Zeichen *Our Reference*
ZJL-- 12311991 006

Ausstellungsdatum
30.01.2019

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+A1+A12
EN 60601-1-3:2008+A1
EN 60601-1-6:2010+A1
EN 60601-2-54:2009+A1

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 Digital Radiography System, wie Blatt 0001 (as page 0001)

UMDNS Code 18-430

Änderungen (Changes)

Prüfgrundlage: EN 60601-1:2006+A11+A12
(Test Requirement) EN 60601-1-3:2008
EN 60601-2-54:2009
ändert sich in: (siehe oben)
(changed to) (see above)

Ergänzung (Addition)

Prüfgrundlage: EN 60601-1-6:2010+A1
(Test Requirement)

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.

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>



Zertifizierungsstelle

Tatsuhiko Nakada

Shimadzu Corporation

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

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

Date: 25 February, 2020
Our ref.: 150116422
Your ref.: ZCBR-19A067/068

Approval of modification for Digital Radiography System

Type Designation : Digital Radiography System RADspeed Pro
General Radiography System RADspeed Pro

License No. : I 50279308
Test Report No. : 12311991 007

Dear Mr. Nakata,

We hereby recognise the modifications for your certified products as requested in your Notice of Alteration dated 2020.01.31

Please find enclosed a copy of notice of Alterations/modification, authorised by us, stamped "Genehmigt/Approved" and dated 2020-02-20

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: Medical - Medical Safety Testing



Yasuaki Matsumoto
Senior Project Engineer



Shinji Onishi
Senior Project Engineer

Enclosure