

THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**IQNet and its partner  
CISQ/CERTIQUALITY S.r.l.**

**LASCOD S.P.A. (LABORATORI  
SCIENTIFICI ODONTOIATRIA)**

IT - 50019 SESTO FIORENTINO (FI) - VIA L. LONGO, 18

has implemented and maintains a  
**Quality Management System**  
which fulfills the requirements of the following standard

**ISO 13485:2003**

for the following activities

Code **EA 12**

Design, production, also on behalf of third parties, and distribution  
of medical devices for dentistry and materials based on alginate and polymeric for taking impressions and realization of  
medical devices.

in the following operative units

IT - 50019 SESTO FIORENTINO (FI) - VIA L. LONGO, 18

Issued on: **2013-06-27**

Certified since: **2010-06-29**

Expire on: **2016-06-26**

Registration number: **IT-56908**

*Kopija tikra*

**Vitalijus Striūžas**  
Direktorius



**Michael Drechsel**  
President of IQNET



**Ing. Claudio Provetti**  
President of CISQ

**IQNet Partners\*:**

- AENOR Spain AFNOR Certification France AIB-Vincotte International Belgium ANCE-SIGE Mexico APCER Portugal CCC Cyprus
- CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany DS Denmark
- FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico INNORPI Tunisia
- Inspecta Certification Finland IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway
- NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SH Israel SIQ Slovenia SIRIM QAS International Malaysia
- SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

**IQNET**  
Tarptautinis Sertifikavimo Tinklas  
**SERTIFIKATAS**

**IQNET** ir jo partneris  
CISQ/CERTIQUALITY s.r.l.

Mes patvirtiname kad įmonė :

**LASCOD S.P.A.**

IT-50019 Sesto Fiorentino (FI) – via L.Longo, 18

Įdiegta ir naudojama kokybės vadybos sistema

**UNI EN ISO 13485:2003**

Srityse kodas EA 12:

**Odontologijos prietaisų ir medžiagų pagamintų alginato ir polimero pagrindų skirtų  
dantų atspaudams, projektavimas ir gamyba, taip pat ir trečiųjų šalių vardu, ir prekyba**

Padalinyje adresu  
IT-50019 Sesto Fiorentino (FI) – via L.Longo, 18

Išdavimo data: 2013-06-27  
Pirmo išdavimo data: 2010-06-29  
Galiojimo data: 2016-06-26

IQNET prezidentas

Michael Drechsler

CISQ prezidentas

Claudio Provetti



*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius



**DICHIARAZIONE DI CONFORMITA' CE – GENERICA**  
**CE GENERIC DECLARATION OF CONFORMITY**  
**MODULO / FORM Rev. 00 - 28.02.2012**

**ASA DENTAL Spa dichiara sotto la propria responsabilità**  
**che**  
*ASA DENTAL Spa declare under its responsibility*  
**that**

**i dispositivi medici da essa fabbricati, soddisfano le disposizioni applicabili del DL 24 febbraio 1997, n. 46. Attuazione della Direttiva 93/42/CEE, concernente i dispositivi medici come emendato dal decreto legislativo 25 gennaio 2010, n. 37, Attuazione della direttiva 2007/47/CE.**

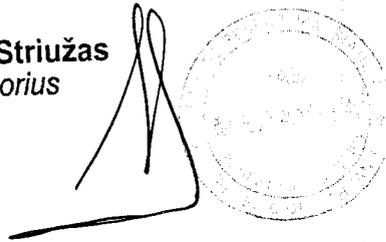
*the medical devices manufactured by ASA DENTAL meet the provisions of DL 24 February 1997, No 46. Implementation of Directive 93/42/EEC concerning medical devices as amended by Legislative Decree 25 January 2010, No 37, Implementation of Directive 2007/47/EC.*

Bozzano 10/07/2012  
Il Direttore Generale  
Alessandro Malfatti



*Kopije tikene*

Vitalijus Striužas  
Direktorius



EFFORT DIVISIONE  
STABILIZZANTI/INLAZISTI

Tel. +39 0584 938305 - Fax +39 0584 938979  
Via del Crocchio, 60 - Bozzano - 55054 Massarosa (Lu)  
Via delle Piogge, 1/A - Monto - 55074 Capannesi (Lu)

BANCHE/BANKE

Intesa San Paolo SpA Viareggio - IBAN: IT 41 0 0206 2680010000900033 - BIC: BCITIT33  
UniCredit SpA Viareggio - IBAN: IT 33 0 02008 24800300004648003 - SWIFT: UNCRIT33  
Monte dei Paschi di Siena Viareggio - IBAN: IT 09 1 01010 2480100000419364 - BIC: PASIT33

CE BENDRA ATITIKTIES DEKLARACIJA  
Forma Rev.00-28.02.2012

ASA dental s.p.a., savo atsakomybe deklaruoja kad :

Medicinos prietaisai gaminami ASA DENTAL atitinka ES medicinos prietaisų  
direktyvos 93/42/CEE (1997m. Vasario 24 d.) reikalavimus su pakeitimais padarytais  
2010 m. sausio mėn. 25d., vykdant direktyvos 2007/47/EC nuostatas.

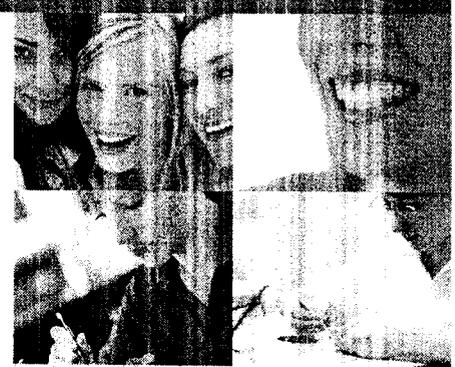
Bozzano 10/07/2012

Generalinis direktorius  
Alessandro Malfatti

*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius





Morsa Wachswarenfabrik GmbH - Nordstraße 3 - 86381 Krumbach

MORSA GmbH

Nordstraße 3  
D-86381 Krumbach (Germany)

Tel.: +49 (08282) 80044-0

Fax: +49 (08282) 80044-33

E-Mail: info@morsa.de

www.morsa-dental.de



## DECLARATION OF CONFORMITY

(in accordance with Medical device directive 93 / 42 EEC)

## EG - KONFORMITÄTSERKLÄRUNG

DECLARATION DE CONFORMITE

Wir / We / Nous / Noi

**MORSA Wachswarenfabrik Sallinger GmbH**  
**Nordstraße 3, 86381 Krumbach (Schwaben), Germany**

erklären in alleiniger Verantwortung, dass  
declare on our own responsibility that the following Class I Products  
declarons sous notre propre responsabilite que  
dichiariamo sotto propria responsabilita che

die Medizinproduktegruppe Name / name / nom / nome:

**„Modellierwachs in Platten“**

den Anforderungen des Anhang I der Richtlinie 93 / 42 / EWG entspricht.  
complies with the Medical Devices Directive 93 / 42 / EEC Appendix I  
remplit le exigence de la 93 / 42 / CEE qui le concernait appendice I  
e conforme le esigenze delle Direttiva 93 / 42 / CEE che lo riguardano appendice I.

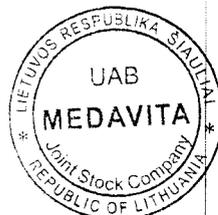
Krumbach, den 6.6.2012

Place, date **MORSA Wachswarenfabrik Sallinger GmbH** Quality management

Die zuständige Überwachungs-Behörde ist die Regierung von Schwaben (Code DE/CA 67).

*Kopija tikra*

**Vitalijus Striužas**  
Direktorius



MORSA Gmbh

## **CE Atitikties deklaracija**

(pagal Medicinos Prietaisų Direktyvą 93/42/EEB)

Mes

Morsa Wachswarenfabrik Sallinger GmbH  
Nordstrasse 3, 86381 Krumbach, (Švabijos regionas) Vokietija

Su pilna atsakomybe deklaruojame, kad

Medicinos prietaisų grupė:

### **„Baziniai modeliavimo vaškai plokštelėse“**

Atitinka EB Medicinos prietaisų Direktyvos 93/42/EEB I priedo reikalavimus.

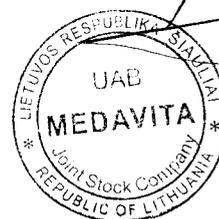
Krumbach, 2012.06.06  
(vieta ir data)

Morsa Wachswarenfabrik Sallinger GmbH                      Kokybės skyrius

Kompetetinga kontroliuojanti institucija yra Švabijos vyriausybė (kodas DE/CA 67)

*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius





Certificate GB98/12223

The management system of

# Stoddard Manufacturing Co. Ltd

Blackhorse Road, Letchworth Garden City,  
Hertfordshire, SG6 1HB, UK

has been assessed and certified as meeting the requirements of



## ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Manufacture and distribution of brushes, polishers and rotary instruments for dentistry, surgery and chiropody. Manufacturer and distributor of brushes, polishers, rotary and handheld instruments, sterile blades and scalpels for dentistry, surgery and chiropody.**

This certificate is valid from 16 February 2013 until 16 February 2016 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 16 February 2016  
Issue 11. Certified since 16 February 1998

*Kopija tikra*

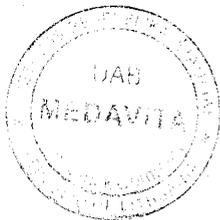
Authorised by

**Vitalijus Striužas**  
Direktorius



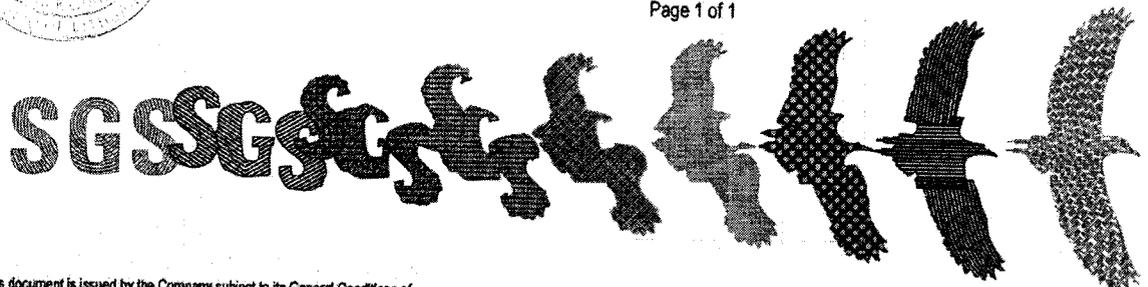
005

SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



SGS 13485-2 0612

Page 1 of 1



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SGS Sertifikatas GB98/12223

Šiuo sertifikatu patvirtiname, kad

Stoddard Manufacturing Co. Ltd  
Denturax Works Icknield Way,  
Letchworth, Herts, SG6 4AH, UK

Buvo patikrinta ir nustatyta kad kokybės vadybos sistema atitinka

ISO 13485:2003  
EN ISO 13485:2012

reikalavimus produktams:

odontologiniai ir chirurginiai šepetėliai, polyrų, gražtai, laikikliai, sukamiesiems ir rankiniams instrumentai skirti naudoti burnos ertmėje. Sterilūs skalpeliai ir ašmenys.

Šis sertifikatas galioja nuo 2013 m. vasario mėn. 16 d. iki 2016 vasario mėn. 16 d., atliekant pakartotinius auditus.

Atnaujinimo auditas turi būti atliktas iki 2016 m. vasario mėn. 16 d.

Sertifikuota nuo 1998 m. vasario mėn. 16 d.

Notifikuotos įstaigos Nr. 0120

Atsakingas asmuo

SGS United Kingdom Ltd. Systems&Services Certifikation  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t. +44(0)1934 522917 f. +44(0)1934 522137 [www.sgs.com](http://www.sgs.com)

SGS 13485-2 0612

Lapas 1 iš 1



*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius



**Intertek**

Certificate Number  
511 CE

Initial Certification Date  
03 December 2001

Certificate Issue Date  
15 February 2012

Certificate Expiry Date  
02 December 2016

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

*This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.*

*AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited.*

*AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.*

**AMTAC Certification Services Limited**  
Davy Avenue  
Knowlhill  
Milton Keynes  
MK5 8NL, UK  
Telephone  
+44 (0)1908 857 750  
Email: [acsl@intertek.com](mailto:acsl@intertek.com)

# EC Certificate

**PRODUCTION QUALITY ASSURANCE**  
**Directive 93/42/EEC for Medical Devices, Annex V**

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

**Organization:**

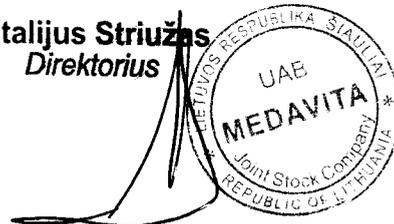
**MR DENTAL SUPPLIES LIMITED**

4 Manor Way, Old Woking, Surrey, GU22 9JX

Artificial acrylic teeth  
Denture base materials

*Kopije tikra*

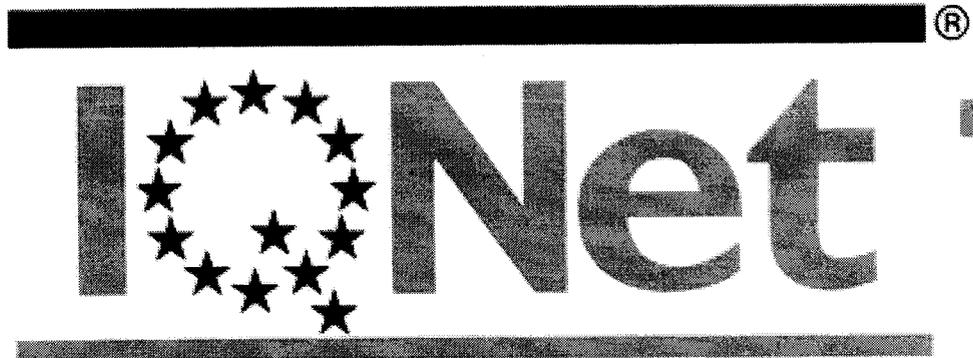
**Vitalijus Striužis**  
Direktorius



**Authorized Signatory:**

**AMTAC Certification Services Limited, Milton Keynes, UK**

*This certificate is the property of Intertek Certification Services Ltd*



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**IQNet and its partner  
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SCIENTIFICI ODONTOIATRIA)**

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**ISO 13485:2003**

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of medical devices for dentistry and materials based on alginate and polymeric for taking impressions and realization of  
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in the following operative units

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Issued on: **2013-06-27**  
Certified since: **2010-06-29**  
Expire on: **2016-06-26**

Registration number: **IT-56908**

*Kopija tikra*

**Vitalijus Striūžas**  
Direktorius



*Michael Drechsel*

*President of IQNET*



*Ing. Claudio Provetti*

*President of CISQ*

**IQNet Partners\*:**

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- CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany DS Denmark
- FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico INNORPI Tunisia
- Inspecta Certification Finland IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway
- NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SH Israel SIQ Slovenia SIRIM QAS International Malaysia
- SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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**IQNET**  
Tarptautinis Sertifikavimo Tinklas  
**SERTIFIKATAS**

**IQNET** ir jo partneris  
CISQ/CERTIQUALITY s.r.l.

Mes patvirtiname kad įmonė :

**LASCOD S.P.A.**

IT-50019 Sesto Fiorentino (FI) – via L.Longo, 18

Įdiegta ir naudojama kokybės vadybos sistema

**UNI EN ISO 13485:2003**

Srityse kodas EA 12:

**Odontologijos prietaisų ir medžiagų pagamintų alginato ir polimero pagrindu skirtų  
dantų atspaudams, projektavimas ir gamyba, taip pat ir trečiųjų šalių vardu, ir prekyba**

Padalinyje adresu  
IT-50019 Sesto Fiorentino (FI) – via L.Longo, 18

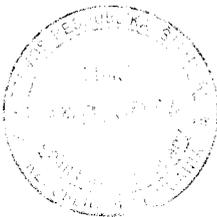
Išdavimo data: 2013-06-27  
Pirmo išdavimo data: 2010-06-29  
Galiojimo data: 2016-06-26

IQNET prezidentas

Michael Drechsler

CISQ prezidentas

Claudio Provetti



*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius



**ASA DENTAL**

Asa Dental S.p.A. unipersonale  
Via Valenzano di Sopra, 60  
Sozzano - 55054 Massarosa (Lu) - Italy  
Tel. +39 0584 938305 - 93863 - 938806  
Fax +39 0584 937167 - 938979  
asadental@asadental.it  
www.asadental.it - www.asadental.com

**DICHIARAZIONE DI CONFORMITA' CE - GENERICA**  
**CE GENERIC DECLARATION OF CONFORMITY**  
**MODULO / FORM Rev. 00 - 28.02.2012**

**ASA DENTAL Spa dichiara sotto la propria responsabilità**  
**che**  
*ASA DENTAL Spa declare under its responsibility*  
**that**

**i dispositivi medici da essa fabbricati, soddisfano le disposizioni applicabili del DL 24 febbraio 1997, n. 46. Attuazione della Direttiva 93/42/CEE, concernente i dispositivi medici come emendato dal decreto legislativo 25 gennaio 2010, n. 37, Attuazione della direttiva 2007/47/CE.**

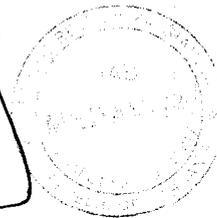
*the medical devices manufactured by ASA DENTAL meet the provisions of DL 24 February 1997, No 46. Implementation of Directive 93/42/EEC concerning medical devices as amended by Legislative Decree 25 January 2010, No 37, Implementation of Directive 2007/47/EC.*

Bozzano 10/07/2012  
Il Direttore Generale  
Alessandro Malfatti



*Kopije tikros*

**Vitalijus Striužas**  
Direktorius



EXPORT DIVISION  
STABLIMENTAI/PLANTS  
BANCHE/BANKS

Tel. +39 0584 937163 - Fax +39 0584 938979  
Via del Crocchio, 60 - Sozzano - 55054 Massarosa (Lu)  
Via delle Piogge, 1/A - Montre - 55014 Capannori (Lu)  
Intesa San Paolo SpA Viareggio - IBAN: IT 41 0 63066 26800 1000000000003 - BIC: IBCITM4270  
UniCredit SpA Viareggio - IBAN: IT 34 0 02108 24502 000004648023 - SWIFT: UNICRIT43C SH  
Monte dei Paschi di Siena Viareggio - IBAN: IT 09 12 01030 24807 0000049384 - BIC: PASCOM33

COMPANY WITH QUALITY MANAGEMENT  
SYSTEM CERTIFIED BY DNV  
= ISO 9001:2008 =

CE BENDRA ATITIKTIES DEKLARACIJA  
Forma Rev.00-28.02.2012

ASA dental s.p.a., savo atsakomybe deklaruoja kad :

Medicinos prietaisai gaminami ASA DENTAL atitinka ES medicinos prietaisų  
direktyvos 93/42/CEE (1997m. Vasario 24 d.) reikalavimus su pakeitimais padarytais  
2010 m. sausio mėn. 25d., vykdamt direktyvos 2007/47/EC nuostatas.

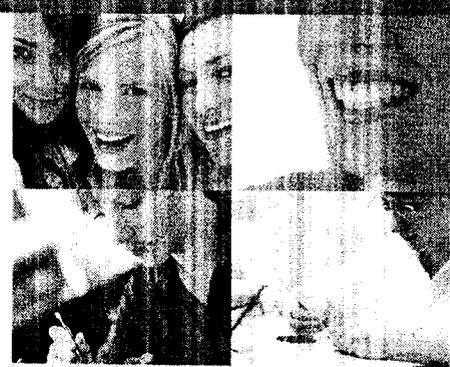
Bozzano 10/07/2012

Generalinis direktorius  
Alessandro Malfatti

*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius





Morsa Wachswarenfabrik GmbH - Nordstraße 3 - 86381 Krumbach

MORSA GmbH

Nordstraße 3  
D-86381 Krumbach (Germany)

Tel.: +49 (0)82 82) 8 00 44-0

Fax: +49 (0)82 82) 8 00 44-33

E-Mail: info@morsa.de

www.morsa-dental.de



## DECLARATION OF CONFORMITY

(in accordance with Medical device directive 93 / 42 EEC)

## EG - KONFORMITÄTSERKLÄRUNG

## DECLARATION DE CONFORMITE

Wir / We / Nous / Noi

**MORSA Wachswarenfabrik Sallinger GmbH**  
**Nordstraße 3, 86381 Krumbach (Schwaben), Germany**

erklären in alleiniger Verantwortung, dass  
declare on our own responsibility that the following Class I Products  
declaronos sous notre propre responsabilite que  
dichiariamo sotto propria responsabilita che

die Medizinproduktegruppe Name / name / nom / nome:

**„Modellierwachs in Platten“**

den Anforderungen des Anhang I der Richtlinie 93 / 42 / EWG entspricht.  
complies with the Medical Devices Directive 93 / 42 / EEC Appendix I  
remplit le exigence de la 93 / 42 / CEE qui le concernait appendice I  
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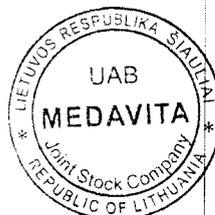
Krumbach, den 6.6.2012

Place, date **MORSA Wachswarenfabrik Sallinger GmbH** Quality management

Die zuständige Überwachungs-Behörde ist die Regierung von Schwaben (Code DE/CA 67).

*Kopija tikra*

**Vitalijus Striužas**  
Direktorius



MORSA GmbH

**CE Atitikties deklaracija**

(pagal Medicinos Prietaisų Direktyvą 93/42/EEB

Mes

Morsa Wachswarenfabrik Sallinger GmbH  
Nordstrasse 3, 86381 Krumbach, (Švabijos regijonas) Vokietija

Su pilna atsakomybe deklaruojame, kad

Medicinos prietaisų grupė:

**„Baziniai modeliavimo vaškai plokštelėse“**

Atitinka EB Medicinos prietaisų Direktyvos 93/42/EEB I priedo reikalavimus.

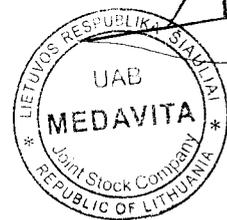
Krumbach, 2012.06.06  
(vieta ir data)

Morsa Wachswarenfabrik Sallinger GmbH                      Kokybės skyrius

Kompetetinga kontroliuojanti institucija yra Švabijos vyriausybė (kodas DE/CA 67)

*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius



Certificate GB98/12223



The management system of

# Stoddard Manufacturing Co. Ltd

Blackhorse Road, Letchworth Garden City,  
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has been assessed and certified as meeting the requirements of

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Re certification audit due before 16 February 2016  
Issue 11. Certified since 16 February 1998

*Kopije tikra*

Authorised by

**Vitalijus Striužas**  
Direktorius

SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0612

Page 1 of 1



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SGS Sertifikatas GB98/12223

Šiuo sertifikatu patvirtiname, kad

Stoddard Manufacturing Co. Ltd  
Denturax Works Icknield Way,  
Letchworth, Herts, SG6 4AH, UK

Buvo patikrinta ir nustatyta kad kokybės vadybos sistema atitinka

ISO 13485:2003  
EN ISO 13485:2012

reikalavimus produktams:

odontologiniai ir chirurginiai šepetėliai, polyrų, gražtai, laikikliai, sukamiesiems ir rankiniams instrumentai skirti naudoti burnos ertmėje. Sterilūs skalpeliai ir ašmenys.

Šis sertifikatas galioja nuo 2013 m. vasario mėn. 16 d. iki 2016 vasario mėn. 16 d., atliekant pakartotinius auditus.

Atnaujinimo auditas turi būti atliktas iki 2016 m. vasario mėn. 16 d.

Sertifikuota nuo 1998 m. vasario mėn. 16 d.

Notifikuotos įstaigos Nr. 0120

Atsakingas asmuo

SGS United Kingdom Ltd. Systems&Services Certifikation  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t. +44(0)1934 522917 f. +44(0)1934 522137 [www.sgs.com](http://www.sgs.com)

SGS 13485-2 0612

Lapas 1 iš 1



*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius

**Certificate Number**  
511 CE

**Initial Certification Date**  
03 December 2001

**Certificate Issue Date**  
15 February 2012

**Certificate Expiry Date**  
02 December 2016

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

*This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.*

*AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited.*

*AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.*

**AMTAC Certification Services Limited**  
Davy Avenue  
Knowlhill  
Milton Keynes  
MK5 8NL, UK  
Telephone  
+44 (0)1908 857 750  
Email: [acsl@intertek.com](mailto:acsl@intertek.com)

# EC Certificate

**PRODUCTION QUALITY ASSURANCE**  
**Directive 93/42/EEC for Medical Devices, Annex V**

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

**Organization:**

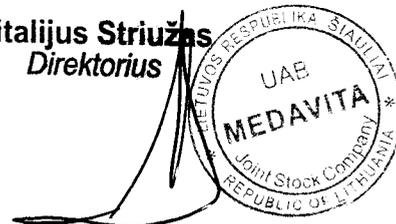
**MR DENTAL SUPPLIES LIMITED**

4 Manor Way, Old Woking, Surrey, GU22 9JX

Artificial acrylic teeth  
Denture base materials

*Kopije tikra*

**Vitalijus Striužas**  
Direktorius



**Authorized Signatory:**

**AMTAC Certification Services Limited, Milton Keynes, UK**

*This certificate is the property of Amtac Certification Services Ltd*

Intertek

Sertifikato numeris

511 A CE

## EB Sertifikatas

Pirmo sertifikavimo data

Gamybos kokybės užtikrinimas

2001 gruodžio 3d.

EEB medicinos prietaisų direktyva 93/42, V priedas/OBL/

Sertifikato išdavimo data

2012 vasario 15d.

Sertifikatas galioja

2016 gruodžio 2d.

Mes patvirtiname, gamybos kokybės užtikrinimo sistemą patikrinimą buvo atliktas pagal Jungtinių Karalystės teisės aktų ir pagal EEB direktyvos 93/42 medicinos prietaisams V priede turimus mūsų prekinio ženklo reikalavimus. Mes patvirtiname, kad gamybos kokybės sistema atitinka aukščiau išvardintus teisės aktus ir suteikiama organizacijai žemiau išvardintus produktus žymėti CE 0473.

Organizacija:

**MR DENTAL SUPPLIES LIMITED**

4 Manor Way, Old Woking, Surrey, GU22 9JX

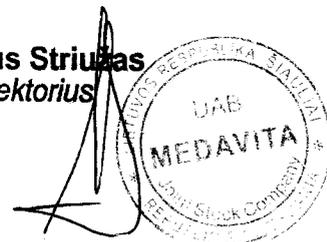
Dirbtiniai akriliniai dantys

*Vitalijus Striukas*

Medžiagos protezų bazėms

**Vitalijus Striukas**  
Direktorius

Įpareigotas pasirašyti



AMTAC Certification Services Limited, Milton Keynes, UK

Sertifikuojanti organizacija, palaiko šiame sertifikate nurodytus reikalavimus ir turi teisę reguliariai tikrinti ir vertinti kaip Notifikuojanti Įstaiga. Šis sertifikatas yra skirtas išskirtiniam AMTAC klientui pagal AMTAC ir jo kliento susitarimą. AMTAC atsakomybė apribota susitarimų sąlygomis. AMTAC neprisiima atsakomybės bet kuriai šaliai dėl nuostolių, išlaidų arba žalos dėl šio sertifikato panaudojimo, išskyrus pagal susitarimą su klientu. Tik klientui leidžiama kopijuoti ir platinti šį sertifikatą. Bet koks AMTAC vardo panaudojimas reklamos, testavimo, tyrimo tikslais turi būti su AMTAC suderintas raštiškai. AMTAC Certification Services Limited yra Notifikuotoji Įstaiga sutinkamai su EEB 93/42 Direktyva medicinos prietaisams, identifikacijos nr. 0473

AMTAC Cerification Services Limited, Davy Avenue, Knowihill Milton Keynes, MK5 8NL, UK. +44 /0/ 1908 857 750, e-mail: acsl@intertek.com



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Heraeus Kulzer GmbH**  
Grüner Weg 11  
63450 Hanau  
Deutschland

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

**Design and Development, Manufacture and Distribution  
of dental products  
(see attachment for sites included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2003 + AC:2009

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

Certificate Registration No.: SX 60037937 0001

An audit was performed. Report No.: 21158216 003

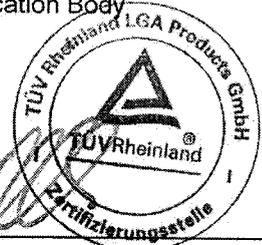
This Certificate is valid until: 03.02.2016



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-995.00.01-46

*Kopije tikra*

Certification Body



**Vitalijus Striužas**  
Direktorius

Date 02.03.2011



Dipl.-Ing. D. Meier

**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>

TUV Rheinland

Sertifikatas

Sertifikavimo įstaiga  
TUV Rheinland LGA Products GmbH

Patvirtina kad įmonė Heraeus Kulzer GmbH  
Gruner Weg 11  
63450 Hanau  
Vokietija

Įdiegė ir naudoja kokybės vadybos sistemą medicinos produktams srityse:

Odontologijos prietaisų projektavimas, gamyba ir prekyba

Kuri pilnai atitinka EN ISO 13485:2003+AC:2009

Kokybės vadybos sistema tikrinama kiekvienais metais.

Sertifikato registracijos Nr. SX 60037937 0001  
Audito atlikimo Nr. 21158216 003  
Sertifikatas galioja iki 03.02.2013

Data 02.03.2011

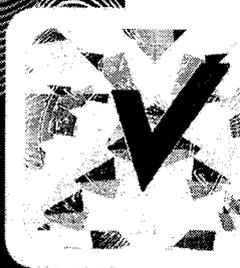
Atsakingas asmuo dip. Inž. D. Meier

TUV Rheinland LGA products GmbH – Tillystrasse 2 – 90431 Nurnberg

*Vertimas tikras*

**Vitalijus Striužas**  
Direktorius





# ZERTIFIKAT

Nr.: TÜV-A-MT-1/13/E015

# TÜV

AUSTRIA

## Qualitätsmanagementsystem - quality management system

Unternehmen:  
*Company:* **Dendia GmbH**  
**Reichsstrasse 126**  
**A-6800 Feldkirch**

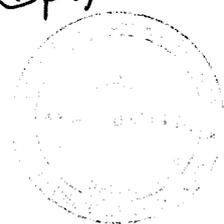
Geltungsbereich:  
*Scope:* **Design und Entwicklung, Produktion und Vertrieb von**  
**Dentalprodukten**  
**Design and development, manufacture and distribution of**  
**dental products**

Norm:  
*Standard:* **EN ISO 13485:2012+AC:2012**  
**Qualitätsmanagementsystem Medizinprodukte**  
**Quality management system medical devices**

Bemerkungen:  
*Remarks:* --

Hiermit bescheinigt die TÜV Austria Services GmbH, dass das Qualitätsmanagementsystem im Zuge eines Audits überprüft wurde und im angeführten Geltungsbereich den Anforderungen der oben angeführten Normengrundlage entspricht.  
*TUV Austria Services GmbH certifies that the quality management system in the above mentioned scope has been examined and meets the relevant requirements of the above mentioned standard.*

*Kopija tikra*



**Vitalijus Striužas**  
*Direktorius*

**MTZert2013-**  
**0223LUS**

Bericht Nr:  
Report No.:

**19.08.2003**

Erstausstellung  
First issue

**02.08.2013**

Datum der Ausstellung  
Date of issue



**Dipl.-Ing. Dr. Robert Messner**

Zertifizierungsbeauftragter  
*Certification representative*

**01.08.2016**

Ende der Gültigkeit  
*End of validity*

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | 證書 | 인증서



Auszugsweise Vervielfältigung nur mit Genehmigung des TÜV Austria gestattet  
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QFM-MT-QM30\_Zertifikat\_13485 Rev. 02

**TÜV AUSTRIA SERVICES GMBH** | benannte Stelle - notified body | ID-Nr.0408  
Akkreditierte Prüf-, Inspektions- und Zertifizierungsstelle - Accredited Testing, Inspection and Certification body  
1015 Wien | Krugerstraße 16 | Tel:+43 (0)1 610 91-6502 | Fax:+43-(0)1-610 91-6505 | E-Mail:mt-zert@tuv.at | www.tuv.at/medizin

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**SERTIFIKATAS**  
Nr. : TUV –A-MT-1/13/E015

TUV  
Austria

Kokybės vadybos sistema

Įmonė: **Dendia Werk GmbH, A-6800 Feldkirch, Munkafeld 2**

Sritis: **odontologijos produktų kūrimas ir vystymas, gamyba ir prekyba**

Standartas: **EN ISO 13485:2012+AC:2012**

Pastabos:

TUV Austria Services GmbH šiuo raštu patvirtina, kad audito metu buvo patikrinta kokybės vadybos sistema ir buvo nustatyta, kad atitinka auksčiau išvardinto standarto reikalavimams.

Pranešimo Nr. 10MT0008LUS

Pirmo išdavimo data: 19.08.2003

Dokumento išdavimo data: 02.08.2013

Galioja iki: 01.08.2016

Dipl. Inžinierius Michael Polzleitner  
Sertifikavimo įstaigos atsakingas asmuo

*Vitalijus Striužas*

**Vitalijus Striužas**  
Direktorius

