

Auxein Medical

AUXEIN MEDICAL

103, First Floor, Jyoti Bhawan Commercial Complex Behind Batra Cinema, Dr. Mukherjee Nagar New Delhi 110009, INDIA Tel: +91-011-27651341 Fax: +91-011-27651344

Email: info@auxeinmedical.com Website: www.auxeinmedical.com

JAB "OSTECA"

Lithuania

Vilniaus g. 18

Klaipėda

Issued in Zlin, on 12 February 2015

LETTER OF AUTHORIZATION

We hereby certify that UAB OSTECA / Lithuania is the exclusive approved agent for Auxein Medical in the market of Lithuania.

UAB OSTECA / Lithuania is authorized to sell all products and other appliances manufactured by our company in Lithuania.

General manager

Latif Murat YILMAZ

Kopija tikra

2015-06-26

Vadybininkas
Vidas Ročys



Vertimas iš anglų kalbos

Auxen Medical

Issued in Zlin, on 12 February 2015

UAB "OSTECA"
Alytaus g.18
Klaipėda
Lietuva

ĮGALIOJIMAS

Tai kam gali būti svarbu

Mes tokiu būdu pažymime, jog UAB "Osteca", Klaipėda, Lietuva, yra mūsų pardavėjas, išskirtinis atstovas Lietuvos rinkai.

UAB "Osteca" yra įgaliota pardavinėti visą, mūsų kompanijos gaminamą produkciją ir kitus priedus Lietuvoje.



2015-06-26

Vadybininkas
Evaldas Ročys

AUXEIN MEDICAL



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 4825-2014-CE-IND-NA

This is to certify that the Quality Management System of

Auxein Medical Private Limited

Plot No. 169, Secgtor-57, Phase-IV, Kundli Industrial Area,
Sonepat – 131 028, Haryana, India.

for design, production and final product inspection/testing of

Orthopaedic Implants & External Fixators

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 23 October 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Mariann Jeremiassen

Mariann Jeremiassen
Certification Manager



Notified Body No.:
0434

This Certificate is valid until:

23 October 2019



2015 -01- 02

Kopija tikra

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.

DNV BUSINESS ASSURANCE
EC CERTIFIKATAS – VISIŠKO KOKYBĖS ATITIKIMO SISTEMA

Sertifikato Nr. 4825-2014-CE-IND-NA

Šiuo pažymima, kad

Auxein Medical Private Limited

Plot Nr. 169, Secgtor-57, Phase-IV, Kundli Industrial Area, Sonapat – 131 028, Haryana, Indija

Ortopedinių implantų ir išorinių fiksatorių

Dizaino, gamybos ir galutinio produktų tikrinimo/testavimo Kokybės valdymo sistema buvo
įvertinta,
atsižvelgiant į
atitikties įvertinimo procedūras, aprašytas Tarybos Direktyvos 93/42/EEC Medicinos prietaisų
Straipsnyje 11.3.a ir Priede Nr. II, išskyrus 4 dalį (Modulis H) su pakeitimais ir nustatyta, kad jas
atitinka

Vieta ir data

Hovik, 2014m. spalio mėn. 23 d.
DET NORSKE VERITAS CERTIFICATION
AS
Norvegija
Mariann Jeremiassen
Sertifikavimo vadovė

Šis sertifikatas galioja iki

2019 m. spalio mėn. 23 d.

Aud Loken Eiklid
Techninis recenzentas

Notifikuojanti įstaiga Nr.:
0434



PRO-MED

INSTRUMENTE GMBH

CHIRURGISCHE INSTRUMENTE
MEDIZINISCHE GERÄTE

SURGICAL INSTRUMENTS
MEDICAL EQUIPMENT

INSTRUMENTS CHIRURGICAUX
MATÉRIEL MÉDICO-CHIRURGICAL

PRO-MED GmbH · Gänsäcker 9 · D-78532 Tuttlingen

For Presentation to the Competent
Authorities in Lithuania

Tuttlingen, 22/08/2013

Letter of Authority

We hereby certify that :

OSTECA, UAB
Alytaus g. 18
LT - 92307 Klaipėda
Lithuania

are authorised and official distributor for

M/S PRO-MED Instrumente GmbH, D-78532 Tuttlingen

in Lithuania.

M/S. OSTECA UAB, are fully authorized to import, distribute / market, sell, advertise and service our products and to participate in all Government and private Tenders and Enquiries on our behalf for the full range of Surgical Instruments and Medical Equipment manufactured and offered by us.
This agreement is valid for an indefinite period.

PRO-MED Instrumente GmbH

PRO-MED
INSTRUMENTE GMBH
Gänsäcker 9
D-78532 TUTTLINGEN
Telefon +49 7462-204240

Ralph Dinkelmann
International Sales Director, MD



Gänsäcker 9
D-78532 Tuttlingen
Telefon +49 (0)7462 20424-0
FAX +49 (0)7462 20424-90
info@pro-med-tut.de
www.pro-med-tut.de

Sitz der Gesellschaft Tuttlingen
Handelsregister Stuttgart HRB 450249
Geschäftsführer Ralph Dinkelmann,
Jan Dinkelmann
USt-Ident.Nr. DE142927589
Es gelten unsere AGB

Deutsche Bank Tuttlingen Nr. 214968000
BLZ: 65370075 BIC: DEUTDE33
IBAN-Nr. DE22 653 700 750 2149680 00
Commerzbank Tuttlingen Nr. 0275721700
BLZ: 64380011 BIC: DRESDEFF33
IBAN-Nr. DE90 643 800 110 2757217 00



PRO-MED
INSTRUMENTE GMBH

Chirurginiai instrumentai

Medicininė įranga

Pateikimui kompetentingoms
institucijoms Lietuvoje

Tuttlingen, 22/08/2013

Gamintojo įgaliojimas

Tvirtiname, kad:

UAB OSTECA

Alytaus g. 18

LT-92307 Klaipėda

Lietuva

Yra įgaliotas ir oficialus platintojas M/S PRO-MED instrumentų GmbH, Tuttlingen, Lietuvoje.

UAB OSTECA yra pilnai leidžiama importuoti, platinti, pateikti rinkai, parduoti, reklamuoti ir aptarnauti mūsų produktus ir dalyvauti visuose vyriausybiniuose ir privačiuose pirkimuose, parduodant mūsų vardu chirurginius instrumentus ir medicininę įrangą mūsų pagamintą ir pasiūlytą.

Ši sutartis galioja neribotą laiką.


Vaigvilinkas
Evaldas Rožys
Kopija tikrai
2014-06-07

PRO-MED

INSTRUMENTE GMBH

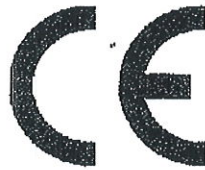
PRO-MED GmbH Gänssäcker 9 D-78532 Tuttlingen

CHIRURGISCHE INSTRUMENTE
MEDIZINISCHE GERÄTE

SURGICAL INSTRUMENTS
MEDICAL EQUIPMENT

INSTRUMENTS CHIRURGICAUX
MATÉRIEL MÉDICO-CHIRURGICAL

Tuttlingen, 26.01.2011



Konformitätserklärung Declaration of Conformity Déclaration de conformité européenne Declaración de conformidad

Wir / We / Nous / Nosotros:

PRO-MED Instrumente GmbH, Gänssäcker 9,
78532 Tuttlingen

erklären in alleiniger Verantwortung, daß die Produkte:
declare under our sole responsibility that the product:
déclarons sous notre seule responsabilité, que les produits:
declara bajo responsabilidad propia, que los productos:

Chirurgische Instrumente
Surgical Instruments
Instruments de Chirurgie réutilisables
Instrumentos quirúrgicos

auf welche sich diese Erklärung bezieht, folgenden einschlägigen Richtlinien der EG entsprechen:
to which this declaration relates, are in conformity with the following relevant regulations:
auxquels se réfère cette déclaration sont conformes aux normes suivantes:
a los que se refieren esta declaración, son conformes a las siguientes normas o directrices:

Medizinprodukterichtlinie 93/42 EWG
Medical Device Directive 93/42 EC
Directive pour dispositifs médicaux 93/42 CEE
Directiva relativa a los productos sanitarios 93/42 CEE

PRO-MED Instrumente GmbH

Jan Dinkermann
General Manager



2011-04-07

Medyminka
Kopija Hkra

Gänssäcker 9
D-78532 Tuttlingen
Telefon +49 (0) 7462 204 24
Fax +49 (0) 7462 204 24 90
Email: pro-med-tut@pro-med-tut.de
Internet: www.pro-med-tut.de

Stb der Gesellschaft Tuttlingen
Handelsregister Stuttgart HRB 450249
Geschäftsführer: Rainer Dinkermann
USt-Ident Nr. DE142667589
FZA Reg. Nr. 8010730
Es gelten unsere AGB

Deutsche Bank Tuttlingen AG: 2 149 686
IBLZ 653700751 DEUT DE 33 600
IBAN-Nr. DE22 6537 0075 0314 9960 00
Gresdner Bank Tuttlingen Nr. 2 757 217
IBLZ 64380011 DRES DE 33 644
IBAN-Nr. DE30 6438 0011 0217 217 40



PRO-MED GmbH Gansacker 9 D-78532 Tuttlingen

PRO-MED
INSTRUMENTE GMBH
Chirurgische Instrumente
Medizinische Geräte

Surgical instruments
Medical Equipment

Chirurginiai instrumentai
Medicininė įranga

Tuttlingen, 2011 01 26

CE

Atitikties deklaracija

Mes:

M/S PRO-MED Instrumente GmbH,
78532 Tuttlingen

prisiimame visišką atsakomybę, kad produktai:

chirurginiai instrumentai

atitinka šias normas:

Medicinos Produktų Direktyva 93/42/CEE

PRO-MED Instrumente GmbH

Jan Dinkelmann
Generalinis direktorius

/parašas/



Vertimas tikras: vertė Elena Solveiga Rimeikienė, UAB "Fokaja", Liepų g. 16, LT-92114 Klaipėda, Lietuva.
Vertėjo atsakomybė pagal LR BK 235str. man žinoma.

