



LETTER OF AUTHORISATION

March 25th, 2019

To whom it may concern,

AUXEIN MEDICAL confirms that the company named below is our authorised exclusive distributor for the territory of Lithuania for all our manufactured products.

UAB Osteca
Danes str. 47,
Klaipeda
Lithuania

The above distributor UAB Osteca is authorized to stock, sell, distribute and solicit orders for orthopedic products manufactured by AUXEIN MEDICAL. The above mentioned distributor is obliged not to sell or disclose any precious information to the third parties, except the information which is allowed and freely accessible via AUXEIN MEDICAL web page. All other business information including the separate agreements, patents, product technical details and procedures, product reference numbers and their marking is strictly forbidden to disclose directly or indirectly, for any other purposes to the third parties.

Regards,



Vertimas iš anglų kalbos

2019 m. kovo mėn. 25 d.

ĮGALIOJIMAS

Tam kam tai gali būti svarbu

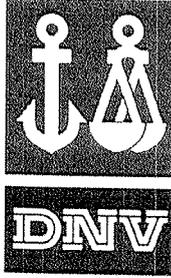
AUXEIN MEDICAL PVT. LTD patvirtina, kad žemiau paminėta kompanija yra oficialus išskirtinis atstovas visiems mūsų gaminamiems produktams Lietuvos teritorijoje.

UAB „Osteca“,
Danės g. 47,
Klaipėda,
Lietuva

Aukščiau paminėtas atstovas, UAB „Osteca“, yra įgaliotas sandėliuoti, pardavinėti, atstovauti bei platinti firmos AUXEIN MEDICAL PVT. LTD ortopedinių priemonių produktus. Aukščiau paminėtas distributorius yra įpareigoti nepardavinėti ir neatskleisti svarbios informacijos tretiesiems asmenims, išskyrus informaciją, kuri yra leistina ir lengvai prieinama AUXEIN MEDICAL PVT. LTD internetiniame puslapyje. Visą kitą verslo informaciją, įskaitant atskirus susitarimus, patentus, produktų techninius parametrus ir procedūras, produktų artikulo numerius ir jų ženklimą yra griežtai draudžiama atskleisti tiesiogiai ar netiesiogiai bet kuriais kitais tikslais tretiesiems asmenims.

Pagarbiai





DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 4825-2014-CE-IND-NA
This Certificate consists of 7 pages

This is to certify that the Quality Management System of

Auxein Medical Private Limited

Plot No. 169, Secgtor-57, Phase-IV, Kundli Industrial Area,
Sonapat – 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
Certification Manager



Notified Body No.:
0434

This Certificate is valid until:

23 October 2019

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digital/signatures 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 100 000. 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.



Cert. No.: 4825-2014-CE-IND-NA
Rev. No.:
Project No.: PRJC-500995-2014-PRC-IND

Sites covered by this certificate

Site Name	Address
Auxein Medical Private Limited	Plot No. 169, Secgtor-57, Phase-IV, Kundli Industrial Area, Sonapat – 131 028, Haryana, India.

EU Representative

JOMISCH, Laan van Keulen 58, 1827 KW Alkmaar, The Netherlands



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



Šalys, kurioms taikomas šis sertifikatas

Šalies pavadinimas	Adresas
Auxein Medical Private Limited	Sklypo Nr. 169, Sektorius 57, Fazė IV, Kundli Industrinė zona, Sonapat – 131 028, Haryana, Indija

Atstovas ES

JOMISH, Laan van Keulen 58, 1827 KW Alkmaar, Olandija

