MEDXPERT
THE CHEST WALL COMPANY

Eschbach, den 16.02.2020

LETTER OF AUTHORIZATION

Sehr geehrte Damen und Herren,

Wir, die Firma MedXpert GmbH mit Sitz in der Max-Immelmann-Allee 19,
79427 Eschbach, Germany,

bestätigen, dass die Firma

OSTECA, UAB
Danes g. 47
92108 KLAIPEDA
LITAUEN

unser Exklusivvertreter für die Implantate-Systeme:

Pectus Excavatum System (P.E.S.)
Strasbourg Thoracic Osteosyntheses System (STRATOS™)
Strasbourg Costal Osteosyntheses System (STRACOS™)

ist und unsere Produkte in Litauen, Lettland und Gebiet Kaliningrad repräsentiert.

Dieses Dokument ist gültig bis einschließlich 31. Dezember 2021.

MedXpert GmbH
Johannes Mussler
Vice-President

LETTER OF AUTHORIZATION

Dear sirs,

MedXpert GmbH, address
Max-Immelmann-Allee Nr. 19
D-79427 Eschbach, Germany

hereby certified that the company

OSTECA, UAB
Danes g. 47
92108 KLAIPEDA
LITAUEN

is our exclusive Representative for the exclusive implant system:

Pectus Excavatum System (P.E.S.)
Strasbourg Thoracic Osteosyntheses System (STRATOS™)
Strasbourg Costal Osteosyntheses System (STRACOS™)

and our products in Lithuania, Latvia and Kaliningrad area represent.

This document is valid until the 31th of December, 2021.

MedXpert GmbH
Johannes Mussler
Vice-President

MedXpert GmbH
Max-Immelmann-Allee 19
D-79427 Eschbach
Germany

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Fax (+ 49) 7634 / 508 563 99
E-Mail info@medXpert.de
WEB www.medXpert.de

Handelsregister Freiburg
HRB 310890
Geschäftsführer: Erhard Reisberg
Ust-IdNr. DE813402258

Volksbank Freiburg eG
BLZ 680 900 00 / Kto. 262 066 00
SWIFT: GENO DE 61 FR1
IBAN: DE44680900000026206600

Vertimas iš anglų kalbos

MEDXPERT

Eschbach, 16.02.2020

ATSTOVAVIMO LAIŠKAS

MedXpert GmbH, adresu
Mx-Immeilmann-Allee Nr 19
D-79427 Eschbach, Vokietija

šiuo raštu tvirtiname, kad kompanija

UAB OSTECA
Danes g. 47
92108 Klaipėda
Lietuva

yra mūsų vienintelis Atstovas atstovauti implantų sistemoms:

Pectus Excavatum System (P.E.S.)

Strasbourg Thoracic Osteosyntheses System (STRATOS)

Strasbourg Costal Osteosyntheses System (STRACOS)

ir mūsų produktus Lietuvos, Latvijos ir Kaliningrado teritorijose.

Šis dokumentas galioja iki Gruodžio 31 d. 2021 metų.

/parašas/

MedXpert GmbH
Johannes Mussler
Vice-Prezidentas

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

MedXpert GmbH
Max-Immelmann-Allee 19
79427 Eschbach
Germany

for the scope

Thoracic Implant System
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-11-20
Valid until	2024-05-26
Registration no.	D1060200015
Report no.	P19-00360-141710
Stuttgart	2019-11-20

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone +49-(0)711-253587-0
Fax +49-(0)711-253587-10
Internet http://www.mdc-ce.de

Attachment of the certificate

No. D1060200015 Date 2019-11-20 Page 1 of 1

Product category	Product	Class	Product code
Thoracic Implant System	STRATOS™ Strasbourg Thoracic Osteosyntheses System	IIb	16-031
	STRACOS™ Strasbourg Costal Osteosyntheses System	IIb	16-031
	P.E.S. Pectus Excavatum System	IIb	16-031

Head of Certification Body

medical device certification mdc

medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49 (0)711-2535 97-0
Fax: +49 (0)711-2535 97-10
internet: http://www.mdc-ce.de

Vertimas iš anglų kalbos

CE Sertifikatas

Patvirtintas dokumentas

mdc medicininių priemonių sertifikavimo tarnyba GmbH
pažymėtas 0483
šiuo pažymi kad

MedXpert GmbH
Max-Immelmnn-Allee 19
79427 Eschbach
Vokietija

produktų kategorijai

Krūtinkaulio Implantų Sistema
(žr. priedą)

Buvo supažindinta ir suteikia

Kokybės Sistemą

Dizainui, gamybai ir galutiniam patikrinimui.

mdc auditas patvirtina kad kokybės sitema atitinka visus reikalavimus pagal

Priedą II – išskyrus 4 Skyrių Tarybos Nutarties 93/42/EEC

1993 Birželio 14 d. susijusių su medicininėmis priemonėmis.

Priežiūra bus atlikta pagal Priedą II, Skyrių 5.

Galioja nuo	2019-11-20
Galioja iki	2024-05-26
Registracijos Nr.	D1060200015
Pranešimo Nr.	P19-00360-141710
Stuttgart	2019-11-20

/parašas/

Sertifikavimo tarnyba

mdc

Vertimas iš anglų kalbos

Priedas prie Sertifikato

Nr. D1060200015 Data 2019-11-20 Psl 1 iš 1

Produkto kategorija	Produktas	Klasė	Produkto kodas
Krūtinkaulio implantų sistema	STRATOS Strasbourg Thoracic Osteosyntheses System	IIb	16-031
	STRACOS Strasbourg Costal Osteosyntheses System	IIb	16-031
	P.E.S. Pectus Excavatum System	IIb	16-031

/parašas/

mdc

ORTHOFIX

Bussolengo (Verona), January 4 2021

TO WHOM IT MAY CONCERN

ORTHOFIX S.R.L. a company organised and established in accordance with the Italian law, with registered office in Via Vittor Pisani n. 16, 20124 Milan, Italy, and principal place of business in Via delle Nazioni n. 9, 37012 Bussolengo (Verona), Italy

HEREBY CERTIFIES THAT

UAB OSTECA, with its principal office based in Danes g. 47, LT-92108, Klaipeda, LT, has been appointed as distributor, effective as of **January 1st 2020**, to distribute in the territories of Latvia and Lithuania, according to the provisions of the Distribution Agreement in place with Orthofix S.r.l., and any and all subsequent amendments thereto.

The present letter is valid until December 31st, 2021.

Sincerely.

ORTHOFIX SRL

Davide Bianchi
CEO and Legal Representative

Vertimas iš anglų kalbos

Bussolengo (Verona), 2021 m. sausio 4 d.

Tam, kam tai gali būti aktualu

ORTHOFIX S.R.L., įmonė, įsteigta ir valdoma pagal Italijos įstatymus, buveinės adresas Via Vittor Pisani Nr. 16, 20124 Milanas, Italija, pagrindinės veiklos adresas Via delle Nazioni Nr. 9, 37012 Bussolengo (Verona), Italija

Šiuo raštu patvirtina, kad

UAB Osteca, įsikūrusi Danės g. 47, LT-92108, Klaipėda, Lietuva, nuo 2020 m. sausio 1 dienos patvirtinta platintoja Lietuvos ir Latvijos teritorijose pagal platinimo sutarties su Orthofix S.r.l. nuostatas ir visus vėlesnius sutarties pakeitimus.

Šis įgaliojimas galioja iki 2021 m. gruodžio 31 d.

Pagarbiai

ORTHOFIX SRL

Davide Bianchi

Generalinis direktorius ir teisinis atstovas

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 052763 0027 Rev. 00

Manufacturer:

Orthofix S.r.l.
Via delle Nazioni, 9
37012 Bussolengo - VR
ITALY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 052763 0027 Rev. 00

Report No.: ITA1502855

Valid from: 2021-02-17
Valid until: 2025-11-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-02-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 052763 0027 Rev. 00

Classification:	IIb
Device Group:	P09120503 - OSTEOSYNTHESIS SCREW-PLATE SYSTEMS
Intended Purpose:	Plates intended to provide bone fixation
Classification:	IIa
Device Group:	Z12139099 - VARIOUS ORTHOPEDIC AND TRAUMATOLOGY INSTRUMENTS - OTHERS
Intended Purpose:	/
The validity of this certificate depends on conditions and/or is limited to the following:	/

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

COPY

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 052763 0025 Rev. 00

Manufacturer:

Orthofix S.r.l.
Via delle Nazioni, 9
37012 Bussolengo - VR
ITALY

Facility(ies):

Orthofix S.r.l.
Via delle Nazioni, 9, 37012 Bussolengo - VR, ITALY

Product Category(ies):

Bone screws (pins), wires for external fixation and implants for osteosynthesis. Instruments for osteosynthesis.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1229259

Valid from: 2019-03-15
Valid until: 2024-03-14

Date, 2019-02-27

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC pažymėjimas
Pilna Kokybės Užtikrinimo Sistema
Direktyva 93/42/EEC Medicinos prietaisams (MDD), Priedas II, išskyrus 4 dalį
(IIa, IIb ar III klasės prietaisams)

Nr.: G1 052763 0025 Rev. 00

Gamintojas:	**Orthofix S.r.l.** Via delle Nazioni Nr. 9 37012 Bussolengo (Verona), Italija
Pagrindinės veiklos adresas:	Orthofix S.r.l. Via delle Nazioni Nr. 9, 37012 Bussolengo (Verona), Italija
Produktų kategorijos	**Kaulų sraigtai (smeigės),** **Vielos išorinei fiksacijai ir osteosintezės implantai** **Osteosintezės instrumentai**

Notifikavimo tarnyba TUV SUD Product Service GmbH tvirtina, kad aukščiau paminėta įmonė yra įdiegusi kokybės valdymo sistemą dizainui, gamybai ir galutinių produktų / produktų kategorijų tikrinimui, vadovaujantis MDD Priedu Nr. II. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos reikalavimus ir yra periodiškai stebima. Norint prekiauti III klasės prietaisais, privalomas papildomas 2 Priedo 4 dalies sertifikatas.
bei atitinka reikalavimus pagal direktyvos priedą II, 4 punktą. Aukščiau nurodytas gamintojas naudoja kokybės užtikrinimo sistemą, kuri atitinka Priedo II, 5 punkto direktyvas. Norėdami rinkoje parduoti III klasės produktus, reikia pažymėjimo priedo II, 4 punkto atitikimo. Žr. pastabas.

Ataskaitos Nr.: ITA1229259

Galioja nuo: 2019-03-15
Galioja iki: 2024-03-14

Data: 2019-02-27

Stefan Preiss

TUV SUD Product Service GmbH yra notifikavimo tarnyba, identifikacinis Nr. 0123

TUV SUD Product Service GmbH. Sertifikavimo tarnyba. Ridlerstrasse 65. 80339 Miunchenas, Vokietija

Białystok, 10-03-2016

OSTECA, UAB
Danes str. 47,
Klaipeda
LITHUANIA

TO WHOM IT MAY CONCER

LETTER OF AUTHORIZATION

This is to certify that:

OSTECA, UAB
Danes str. 47,
LT-92108 Klaipeda,
LITHUANIA

is authorized and has an exclusive right to distribute the MEDGAL production such like osteosynthesis implants, hip joint prostheses, tools, instruments and other production in the Lithuanian market.

This authorization letter is valid for an indefinite period.

LIETUVOS RESPUBLIKA
2016 -03- 10
Osteca
AB "Osteca"

Kopija tikra

CEO

Urszula Borowska-Skarzyńska

MEDGAL sp. z o.o.
PREZES
Urszula Borowska-Skarzyńska

MEDGAL sp. z o.o.
ul. Wąska 59, 15-122 Białystok
tel. +48 85 6632 344
fax +48 85 6632 622
REGON 200737591, NIP 5423237877