MEDXPERT
THE CHEST WALL COMPANY

MedXpert GmbH, Max-Immelmann-Allee 19, 79427 Eschbach – Germany

LETTER OF AUTHORIZATION	LETTER OF AUTHORIZATION
Wir, die MedXpert GmbH (Hersteller) Max-Immelmann-Allee 19, 79427 Eschbach, Germany	We, the MedXpert GmbH (manufacturer) Max-Immelmann-Allee 19, 79427 Eschbach, Germany
bestätigen, dass	confirm that
Osteca UAB Danes str. 47 92108 Klaipeda Litauen	Osteca UAB Danes str. 47 92108 Klaipeda Lithuania
unser autorisierter Fachhändler für unsere Produkte	is our authorized distributor for our products
P.E.S Pectus Excavatum System, Instruments and Implants **STRATOS Strasbourg-Thoracic-Osteosyntheses** System, Instrumente und Implantate **STRACOS Strasbourg-Costal-Osteosyntheses** System, Instrumente und Implantate	**P.E.S Pectus Excavatum** System, Instruments and Implants **STRATOS Strasbourg-Thoracic-Osteosyntheses** System, Instruments and Implants **STRACOS Strasbourg-Costal-Osteosyntheses** System, Instruments and Implants
gemäß den angehängten Produktlisten in Litauen ist.	according to the attached product lists in Lithuania.
MedXpert erklärt die Produkte, bestehend aus Implantate und Instrumente, einschließlich ihrer Verpackung inklusive Etikett, der zugehörigen Gebrauchsanweisung inklusive ihrer Dienstleistung / Service sowie bei Implantaten zusätzlich der Implantat-Ausweis, konform gemäß	MedXpert declares that the products, consisting of implants and instruments, including their packaging including label, the associated instructions for use including their service / service as well as, in the case of implants, additionally the implant identification card, compliant according to
- geltenden europäischen Regularien und Normen MDD und MDR - DIN EN ISO 13485 - Good Manufacturing Practice (GMP)	- applicable European regulations and standards MDD and MDR - DIN EN ISO 13485 - Good Manufacturing Practice (GMP)
und produziert ihre Produkte gemäß den Anforderungen, die sich aus diesen ergeben.	and produces its products in accordance with the requirements arising from these.

MedXpert GmbH
Max-Immelmann-Allee 19
D-79427 Eschbach
Germany
230517-LoA Osteca #25026 Litauen.docx

Telefon (+ 49) 7634 / 508 563 0
Fax (+ 49) 7634 / 508 563 99
E-Mail info@medXpert.de
WEB www.medXpert.de

Handelsregister Freiburg
HRB 310890
Geschäftsführer: Dr. Ulrich Ch. Knapp
Ust-IdNr. DE813402258

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

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MedXpert ist als Hersteller der oben genannten Produkte verantwortlich für die Sicherheit und Leistung dieser.	MedXpert, as the manufacturer of the above products, is responsible for their safety and performance.
MedXpert informiert den autorisierten Fachhändler über alle präventiven oder korrektiven Maßnahmen, die für die gelieferten Produkte durch den autorisierten Fachhändler zu ergreifen sind, wie zum Beispiel Produktrückrufe, und Informationen über unerwünschte Ereignisse.	MedXpert will inform the authorized distributor about any preventive or corrective measures to be taken for the delivered products by the authorized distributor, such as product recalls, and information about adverse events.
MedXpert ist verantwortlich für das Training und die Qualifikation des autorisierten Fachhändlers in Bezug auf die Handhabung und Anwendung der oben genannten Produkte.	MedXpert is responsible for the training and qualification of the authorized distributor regarding the handling and application of the above mentioned products.
Produkte Der autorisierte Fachhändler ist dafür verantwortlich, sicherzustellen, dass	**Products** The authorized distributor is responsible for ensuring that:
(1) ausschließlich von MedXpert autorisierte Vertriebsunterlagen wie Prospekte, Informationen zur Anwendung kommen,	(1) only sales documents such as brochures or other information authorized by MedXpert are used,
(2) von ihm übersetzte Informationen zu den bzw. über die Produkte korrekt und auf dem neuesten Stand sind und von MedXpert autorisiert werden. Dies gilt auch und im Besonderen für Produktaussagen im Internet wie z.B. Website,	(2) any information translated by him regarding or about the products is accurate and up to date and authorized by MedXpert. This also applies in particular to product statements on the Internet, e.g. on the website,
(3) die in seinem Vertriebsgebiet geltenden, nationalen Vorschriften eingehalten werden,	(3) the national regulations applicable in its sales territory are fulfilled,
(4) Vertriebsmitarbeiter, Sub-Unternehmer sowie die Anwender der Produkte in deren Handhabung und Anwendung geschult werden,	(4) their sales staff, sub-distributors and users of the products are trained in their handling and application,
(5) Nicht-Konformitäten und Vorkommnisse dem Hersteller unverzüglich mitgeteilt werden	(5) non-conformities and incidents are reported immediately to the manufacturer

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(6) während sich die Produkte seiner Verantwortung befinden, die Lagerungs- und Transportbedingungen den Vorgaben des Herstellers entsprechen und keine Veränderungen an den Produkten vorgenommen werden,	(6) while the products are under its responsibility, the storage and transport conditions are in accordance with the manufacturer's specifications and no modifications are made to the products,
(7) die Rückverfolgbarkeit der Produkte sichergestellt ist,	(7) the traceability of the products is ensured,
(8) er mit dem Hersteller und den zuständigen Behörden zusammenarbeitet, um sicherzustellen, dass bei Bedarf erforderliche Korrekturmaßnahmen ergriffen werden, um die Konformität des Produkts herzustellen, es vom Markt zu nehmen oder zurückzurufen.	(8) it cooperates with the manufacturer and the competent authorities to ensure that any necessary corrective action is taken, if required, to bring the product into conformity, to withdraw it from the market or to recall it.
Fachhändler Der Fachhändler benennt eine verantwortliche Person in seinem Unternehmen, die für die Entgegennahme und Verteilung, Information und Beantwortung alle produktrelevanten Fragen, die sich aus dem Letter of Authorization (LoA) ergeben, verantwortlich ist.	**Authorized distributor** The authorized distributor has to name a responsible person in his company who is responsible for receiving and distributing, informing and answering all product-relevant questions arising from the Letter of Authorization (LoA).
Der Fachhändler benennt einen Qualitätsmanagementbeauftragten und teilt diesen dem Hersteller mit.	The authorized distributor appoints a quality management representative and informs the manufacturer of this appointment.
Die Gültigkeit dieses Letter of Authorization beläuft sich auf einen Zeitraum von 2 Jahren für die Produkte aus der in der Anlage befindlichen Produktliste. Der Letter of Authorization kann jederzeit widerrufen werden.	The validity of this Letter of Authorization is for a period of 2 years for the products from the product lists in the attachment. The Letter of Authorization may be withdrawn at any time.

Eschbach, 17.05.2023

MedXpert GmbH

Vice President

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Anlagen / attachments:

Produktlisten / Product lists

- 1_1 Produktliste 2023_PES Implantate Vers. 01.pdf
- 1_1 Produktliste 2023_PES Instrumente Vers. 01.pdf
- 1_1 Produktliste 2023_STRATOS Implantate Vers. 01.pdf
- 1_1 Produktliste 2023_STRATOS Instrumente Vers. 01.pdf

Bestätigung / Confirmation

Der autorisierte Fachhändler / The authorized distributor

[redacted]

Name of Responsible Person — e-mail address

Name of Quality Manager — e-mail address

Note: Responsible Person and Quality Manager can be the same person.

Osteca UAB
Danes str. 47
92108 Klaipeda
Lithuania

bestätigt mit seiner Gegenzeichnung der Erhalt und die Einhaltung der LoA / confirms reception and compliance to this LoA with his/her countersignature

OSTECA LTD. — 2023-05-19

Firma / Company — Datum / Date

[redacted] — HEAD MANAGER

Name / Name — ...on / Position

[redacted]

Unterschrift / Signature

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Certificate

mdc medical device certification GmbH
certifies that

MedXpert GmbH
Max-Immelmann-Allee 19
79427 Eschbach
Germany

for the scope

manufacturing, development and sales of surgical implants, instruments, containers for sterilization

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-08-16
Valid until	2025-04-27
Registration no.	D1060200017
Report no.	P23-00315-260809
Stuttgart	2023-08-16

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

MedXpert GmbH Max-Immelmann-Allee 19 79427 Eschbach

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MedXpert GmbH, Max-Immelmann-Allee 19, 79427 Eschbach – Germany

Ladies and Gentlemen,
Dear customers.

In the last few days, we have received an increasing number of inquiries regarding the orientation and information of certification in accordance with the MDR. These requests also include documents that contain a statement on the further maintenance of MedXpert GmbH. We would like to inform you below about the current status.

In principle, MedXpert continues to fulfill the requirements of EN ISO 13485 and MDD (EU) 93/42/EEC. There are no significant changes to the design and intended purpose and there is no unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection. MedXpert will undergo regular surveillance by the Notified Body in April in accordance with EN ISO 13485 and MDD (EU) 93/42/EEC to maintain its certificates.

For the transitional period in accordance with Regulation (EU) 2023/607, the legislator has stipulated that a so-called "Confirmation Letter" is to be issued by the authorities or the Notified Bodies (subordinate to the authorities), which is valid as a certificate until the end of the transitional period and the final entry into force of the MDR.

Obtaining this "Confirmation Letter" is preceded by an extensive process, which MedXpert has been involved in for months. All the necessary applications have been made and the documents submitted.

MedXpert must now wait until the authorities and Notified Body issue the expected "Confirmation Letter" and issue it to MedXpert.

MedXpert has no influence on this procedure and we are therefore currently not in a position to provide you with this document. Nor can we make any statement regarding the time of creation and delivery.

According to the European Union's timetable, the "Confirmation Letter" should be issued by 26.05.2024 at the latest.

You can rest assured that the document will be presented to you immediately and without any delay as soon as we have it.

Thank you for your understanding.

Eschbach, 12.04.2024

ppa. QMR

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

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Declaration of the manufacturer

with regard to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with regard to

- the validity of the certificates issued in accordance with Council Directive 93/42/EEC on medical devices (MDD) (directive certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Name of the manufacturer	MedXpert GmbH
Address and contact information of the manufacturer	Max-Immelmann-Allee 19 D-79427 Eschbach Phone: +49 7634 508 563 0
Single Registration Number (SRN)	DE-MF-000005489

Name of the notified body	mdc medical device certification GmbH □ See attached table
Number of the notified body	0483 □ See attached table
Number of the directive certificate to which this confirmation relates	D1060200015 □ See attached table
Original expiration date as stated in the directive certificate prior to the extension of validity	26.05.2024 □ See attached table
End date of the extended validity/transition period	31.12.2027 Class IIb 31.12.2028 Class I(r) □ See attached table

MedXpert, as manufacturer, declares under sole responsibility:

- for the above-mentioned directive certificate, that the conditions for the legal extension of validity in accordance with Article 120.2 of the MDR are fulfilled and
- for the devices listed in the attached list and MedXpert as their manufacturer, are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above and in the attached table

- Directive Certificate covering the listed medical devices was issued after May 25, 2017, was valid on May 26, 2021 and have not been withdrawn afterwards.
- A formal application for conformity assessment with the notified body in accordance with section 4.3 paragraph 1 of Annex VII of the MDR has been submitted by MedXpert no later than May 26, 2024 for the devices listed in the attached list and a signed written agreement in accordance with section 4.3 paragraph 2 of Annex VII of the MDR is available before September 26, 2024.

➢ **Quality management system (QMS)**

- A QMS in accordance with Article 10(9) of the MDR is in place.

➢ **Medical devices as listed in the attached table**

- The medical devices continue to comply with the MDD.
- There are no significant changes in terms of design and intended use.
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection.

MedXpert GmbH

Eschbach, 23.05.2024

[redacted]

EDXPERT
hest wall company
-Immelmann-Allee 19
79427 Eschbach
l: 07634 - 508 563 0
Fax: 07634 - 508 563 99

ppa.

Attachment
Table of medical devices according to guidelines Certificate

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Table of medical devices

The above manufacturer's declaration applies to the following medical devices:

Identification of medical devices [1]	Number of the Directive certificate to which this confirmation relates	Original expiration date as stated on the directive certificate prior to the extension of validity	Name and number of the notified body that issued the certificate	Name and number of the notified body where the MDR contract was signed	End date of the extended validity / transition period
STRATOS™ Strasbourg Thorax Osteosynthesis system	D1060200015	2024-05-26	mdc medical device certification GmbH / 0483	mdc medical device certification GmbH / 0483	31.12.2027 Class IIb 31.12.2028 Class I(r)
STRACOS TM Strasbourg Costales Osteosynthesis system	D1060200015	2024-05-26	mdc medical device certification GmbH / 0483	mdc medical device certification GmbH / 0483	31.12.2027 Class IIb 31.12.2028 Class I(r)
P.E.S Pectus Excavatum System	D1060200015	2024-05-26	mdc medical device certification GmbH / 0483	mdc medical device certification GmbH / 0483	31.12.2027 Class IIb 31.12.2028 Class I(r)

[1] "*191120-CE ANNEX Certificate EN.pdf*"

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 5
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de