



REMA Medizintechnik GmbH
In Breiten 10
78589 Dürbheim - Germany

REMA Medizintechnik GmbH, In Breiten 10, 78589 Dürbheim - Germany

Tel. +49 (0) 74 24 981053-0
Fax: +49 (0) 74 24 981053-99
E-Mail: info@rema-surgery.de

To whom it may concern

Tuttlingen, June 12th, 2021

AUTHORIZATION LETTER

We hereby confirm that the company:

Osteca, UAB
Danes 47
LT-92108 Klaipeda
Lithuania

Is authorized to act as our distributor and again promotion, sales and marketing our range of products in the country of Lithuania. Osteca UAB ensures the technical services and maintenance of our products, manufactured and distributed by:

REMA Medizintechnik GmbH
In Breiten 10
D-78589 Dürbheim
Germany

This non-exclusive agreement remains valid until 31.12.2022

Sincerely yours


REMA MEDIZINTECHNIK GMBH
In Breiten 10
D-78589 Dürbheim / Tuttlingen
i.A. Telefon 07424 - 981053-0
May-Britt Marx
Area Sales Manager
REMA Medizintechnik GmbH



Kreissparkasse Tuttlingen
SWIFT-BIC: SOLA DE 51 TUT
IBAN DE65643500700000811330
Konto: 81130
Bl.Z. 643 500 70

Deutsche Bank Tuttlingen
SWIFT-BIC: DEUTDESS653
IBAN DE40653700750219031200
Konto : 219031200
Bl.Z 65370075

Ust-IdNr. DE295809605
Steuernummer: 21060/61061
Amtsgericht Stuttgart
HRB 460220

Geschäftsführer: Jobst von Dewitz

Vertimas iš anglų kalbos

REMA SURGERY
Rema Medizintechnik GmbH
In Breiten 10
78589 Durbheim - Vokietija

Suinteresuotiems asmenims

Tuttlingen, 2021 m. birželio 12 d.

Šiuo būdu patvirtiname, kad įmonė

UAB „OSTECA“,
Danės g. 47
Klaipėda LT 92108
Lietuva

Yra įgaliota būti mūsų įgaliotu distributoriumi ir siūlyti, pardavinėti ir reklamuoti mūsų produkciją Lietuvos teritorijoje. UAB Osteca užtikrina techninį aptarnavimą ir techninę priežiūrą produktų, pagamintų:

Rema Medizintechnik GmbH
In Breiten 10
78589 Durbheim
Vokietija

Šis neišskirtinis įgaliojimas galioja iki 2022.12.31

i.A. May-Britt Marx (Ms) | Area Sales Manager

DEWIMED / REMA Medizintechnik GmbH

Phone +49(0)7462 923 9351

Maybritt.marx@dewimed.de

www.DEWIMED.de

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

DEWIMED Medizintechnik GmbH
Unter Hasslen 14
78532 Tuttlingen
Germany

for the scope

Selfholding Retractors

has introduced and applies a

Quality System

for the manufacture of the products concerned and carries out a
final inspection as specified in Annex V, Section 3.

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

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2017-05-14
Valid until	2022-05-14
Registration no.	D1424600002
Report no.	P16-01142-97214
Stuttgart	2017-04-28



Head of Certification Body



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>

CE SERTIFIKATAS

Medicinių prietaisų sertifikavimas GmbH

Notifikavimo numeris 0483

Šiuo raštu pažymi kad

DEWIMED Medizintechnik GmbH

Unter Hasslen 14

78532 Tuttingenas

Vokietija

Atitinka

Kokybės sistemą

Produktų gamybai ir inspekcijai, atitinkančią Priedo nr. V, 3 punktą.

Mdc auditas patvirtina, kad ši kokybės sistema atitinka visus reikalavimus, numatytus

Direktyvos 93/42/EEC

V priedo – 3 punktą

Numatytą 1993 birželio 14 d., taikomą medicininėms priemonėms

Priežiūra bus taikoma kaip numatyta V Priedo 4 punkte.

Galioja nuo	2017 05 14
Galioja iki	2022 05 14
Registracijos Nr.	D1424600002
Pranešimo Nr.	P16-01142-97214
Štutgartas	2017 04 28



EC Certificate

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Notified Body 0483
herewith certifies that

**REMA Medizintechnik GmbH
In Breiten 10
78589 Dürbheim
Germany**

for the scope

**active surgery equipment for endoscopy,
instruments for endoscopy and HF surgery and implants
(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.

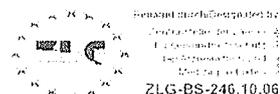
Valid from	2019-03-27
Valid until	2023-07-01
Registration no.	D1040900007
Report no.	P18-00518-118454
Stuttgart	2019-03-27



Head of Certification Body



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mdc



Attachment of the certificate

No. D1040900007

Date 2019-03-27

Page 1 of 1

Product category	Product	Class	Product code
Implants	Interference screw	Iib	16-101
Instruments for endoscopy	Arthroscopy instruments Arthroscopy optic	Ila	10-198
	Cystoscope instruments Cystoscope optic	Ila	11-112
	Hysteroscope instruments Hysteroscope optic	Ila	12-081
	Laparoscope optic	Ila	12-291
	Veress needle	Ila	12-750
	Resectoscope instruments	Ila	13-335
	Sinuscope	Ila	13-396
	Thoracoscope	Ila	14-047
	Suction irrigation cannula	Ila	15-206
	Trocar / Trocar sleeves	Ila	15-260
	Shaver blades (sterile/non sterile)	Ila	17-117
	Ureterorenoscope	Ila	17-690
	Instruments for HF surgery	HF Handles, controlled	Iib
Turning and dismountable instruments with HF connection		Iib	11-779
Electrodes HF surgery		Iib	15-579
Electrodes HF surgery, active electrodes		Iib	16-860

Handwritten signature

Head of Certification Body



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DEWIMED Medizintechnik GmbH
Unter Hasslen 14
78532 Tuttlingen
Germany

for the scope

Surgical Instruments, RF-Instruments, Bone Screws, Neuroimplants
(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

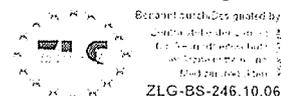
of 14 June 1993 concerning medical devices.

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

Valid from	2018-01-23
Valid until	2022-05-14
Registration no.	D1424600006
Report no.	P16-01143-112734
Stuttgart	2018-01-23


Head of Certification Body

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mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10

Attachment of the certificate

No. D1424600006

Date 2018-01-23

Page 1 of 1

Product category	Product	Class	Product code
Surgical Instruments	Suction and irrigation instruments	Ila	16-883
RF-Instruments	Monopolar and bipolar RF forceps	Ilb	16-206
	Monopolar and bipolar RF electrodes	Ilb	15-579
Bone Screws	Orthodontic screws for the skeletal anchoring of orthodontic appliances	Ilb	16-101
Neuroimplants	Aneurysm clips (permanent and temporary)	III	10-905

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Notified Body 0483

herewith grants

DEWIMED Medizintechnik GmbH

Unter Hasslen 14

78532 Tuttlingen

Germany

for the scope

Aneurysm Clips

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

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

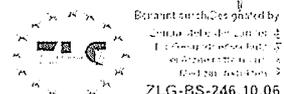
of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex II – excluding section 4 for the above mentioned products.

Valid from	2018-01-23
Valid until	2023-01-23
Registration no.	D1424600005
Report no.	P16-01143-112796
Stuttgart	2018-01-23


Head of Certification Body

medical device certification
mdc



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

DEWIMED Medizintechnik GmbH
Unter Hasslen 14
78532 Tuttlingen
Germany

for the scope

Selfholding Retractors

has introduced and applies a

Quality System

for the manufacture of the products concerned and carries out a
final inspection as specified in Annex V, Section 3.

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

Annex V – Section 3
of the Council Directive 93/42/EEC

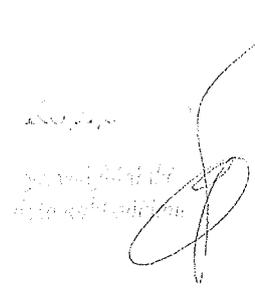
of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2017-05-14
Valid until	2022-05-14
Registration no.	D1424600002
Report no.	P16-01142-97214
Stuttgart	2017-04-28


Head of Certification Body

the medical device certification
mdc



ZLG-BS-246.10.06