EC CERTIFICATE

Number: 2180423CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Eckert & Ziegler BEBIG GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany

For the product category(ies)

Radioactive Sources, Afterloading Systems, Applicators and Treatment Planning Systems for Brachytherapy

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2180423CN, initially dated 28 August 2015
Addendum, initially dated 3 December 2015

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 15 September 2023
Issued for the first time: 3 December 2015
Reissued: 25 October 2018

DEKRA Certification B.V.

[redacted]

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2180423CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Radioactive Sources, Afterloading Systems, Applicators and Treatment Planning Systems for Brachytherapy

Issued to:

Eckert & Ziegler BEBIG GmbH
Robert-Rössle-Strasse 10
13125 Berlin
Germany

This certificate covers the following product(s):

Products of class IIa
Brachytherapy-applicators, Afterloading UMDNS 17-732 includes:
HDR-Afterloading accessories: Intracavitary applicators and accessories
HDR-Afterloading accessories: Oesophagus Set
HDR-Afterloading accessories: Universal applicators and accessories

Needles UMDNS 12-729 includes:
HDR-Afterloading accessories: Interstitial needles and catheters

Products of class IIb
Brachytherapy Radioactive Source UMDNS 17-518 includes:
Eye Applicators, Ruthenium-106

IsoSeed for temporary use on the eye, Iodine-125

Brachytherapy System, Afterloading device UMDNS 17-517 includes:
Afterloader for high dose rate, SagiNova
Applicators, eye UMDNS 10-175 includes:
Applicator for brachytherapy of eye tumour for therapy with Iodine-125 seeds

DEKRA Certification B.V.

[redacted]

Managing Director

Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2180423CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Radioactive Sources, Afterloading Systems, Applicators and Treatment Planning Systems for Brachytherapy

Issued to:

Eckert & Ziegler BEBIG GmbH
Robert-Rössle-Strasse 10
13125 Berlin
Germany

Treatment Planning Systems UMDNS 13-281 includes:
Treatment Planning System SagiPlan
Treatment Planning System HDRplus

Initial date: 3 December 2015

DEKRA Certification B.V.

[redacted]

Managing Director Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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CE SERTIFIKATAS

Numeris: 2180423CE02

Visiškos kokybės užtikrinimo sistema
Pagal 93/42/EEB II Priedą (išskyrus 4 skirsnį)

(Prietaisų klasės IIIb ar III)

Patvirtiname, kad įmonė:

Eckert & Ziegler BEBIG GmbH

Robert-Rossle-Strasse 10
13125 Berlynas
Vokietija

Produktams/produktų kategorijoms:

Brachiterapijos radioaktyvieji šaltiniai, įvedimo sistemos, aplikatoriai ir gydymo planavimo sistemos

DEKRA suteikia teisę naudoti toliau nurodytą EB notifikuotosios įstaigos identifikavimo numerį kartu su CE atitikties ženklu, susijusiu su atitinkamais produktais, atitinkančiais reikalaujamus techninius dokumentus ir atitinkančius jiems taikomus EB direktyvos reikalavimus:

0344

Dokumentai, kurie yra šio sertifikato pagrindas:

Sertifikatas Nr. 2180423CN, pirminė data 2015 m. rugpjūčio 28 d.
Papildytas, pirminė data 2015 m. gruodžio 3 d.

DEKRA patvirtina, kad pirmiau minėtas gamintojas atitinka atitinkamas „Besluit Medische Hulpmiddelen“, Nyderlandų 1993 m.birželio 14 d. Tarybos direktyvos 93/42/EEB dėl medicinos prietaisų, įskaitant visus vėlesnius pakeitimus, nuostatas. Pagal 1993 m. birželio 14 d. Tarybos direktyvos 93/42/EEB II priedo nuostatas gamintojas įdiegė projektavimo, gamybos ir galutinio patikrinimo kokybės užtikrinimo sistemą, kuri yra reguliariai stebima. III klasės prietaisų pateikimui į rinką privalomas papildomas EB projekto tyrimo sertifikatas pagal II priedo 4 dalį.
Reikalinga informacija, susijusi su gamintojo kokybės valdymo sistema, įskaitant įrenginius, ir nuoroda į atitinkamus dokumentus, atitinkamus produktus ir atliktus vertinimus, yra nurodyta pranešime apie sertifikavimą, kuris yra integrali šio sertifikato dalis.

Šis sertifikatas galioja iki: 2023 m. rugsėjo 15 d.
Pirminė data: 2015 m. gruodžio 3 d.
Išleistas: 2018 m. spalio 25 d.

DEKRA sertifikavimas B.V.
/parašas/

d. G.J. Zoetbrood	J.A. van Vugt
Vykdantysis direktorius	Sertifikavimo vadovas

DEKRA sertifikavimas B.V. yra notifikuotoji įstaiga su ID Nr. 0344

DEKRA sertifikavimas B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, Olandija T +31 88 96 83000
F +31 88 96 83100 www.dekra-certification.com Įmonės registracija 09085396

PRIEDAS

Pridedama prie sertifikato: 2180423CE02

CE ženklinimo atitiktis
Mediciniai prietaisai

Brachiterapijos radioaktyvieji šaltiniai, pakrovimo sistemos, aplikatoriai ir gydymo planavimo sistemos

Išduota:

Eckert & Ziegler BEBIG GmbH
Robert-Rossle-Strasse 10
13125 Berlynas
Vokietija

Šis sertifikatas apima šiuos produktus:

IIa klasės produktai
Brachiterapijos aplikatoriai, po apkrovos UMDNS 17-732 apima:
HDR įvedimo priedai: vidinių ertmių aplikatoriai ir priedai
HDR įvedimo priedai: stemplės rinkinys
HDR įvedimo priedai: universalūs aplikatoriai ir priedai

Adatos 12-729:
HDR įvedimo priedai: intersticinės adatos ir kateteriai

IIb klasės produktai
Brachiterapijos radioaktyvusis šaltinis UMDNS 17-518 apima:
Oftalmologiniai aplikatoriai, Rutenis-106

IsoSeed, skirti vienkartiniam naudojimui ant akies, Jodas-125

Brachiterapijos sistemos, įvedimo prietaisas UMDNS 17-517 apima:
Įvedimo prietaisas didelėms dozėms, SagiNova

Oftalmologiniai aplikatoriai 10-175 apima:
Brachiterapijos aplikatoriai akių navikų terapijai su Jodo-125 sėklomis

DEKRA sertifikavimas B.V.
/parašas/
d. G.J. Zoetbrood — Vykdantysis direktorius
J.A. van Vugt — Sertifikavimo vadovas

PRIEDAS

Pridedama prie sertifikato: 2180423CE02

CE ženklinimo atitiktis
Mediciniai prietaisai

Brachiterapijos radioaktyvieji šaltiniai, pakrovimo sistemos, aplikatoriai ir gydymo planavimo sistemos

Išduota:

Eckert & Ziegler BEBIG GmbH
Robert-Rossle-Strasse 10
13125 Berlynas
Vokietija

Gydymo planavimo sistemos UMDNS 13-281 apima:
Gydymo planavimo sistema SagiPlan
Gydymo planavimo sistema HDRplus

Pirminė data: 2015 m. gruodžio 3 d.

DEKRA sertifikavimas B.V.
/parašas/

d. G.J. Zoetbrood	J.A. van Vugt
Vykdantysis direktorius	Sertifikavimo vadovas

DEKRA sertifikavimas B.V. yra notifikuotoji įstaiga su ID Nr. 0344

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Eckert & Ziegler

Eckert & Ziegler
BEBIG GmbH

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Eckert & Ziegler BEBIG GmbH, Robert-Rössle-Straße 10, D-13125 Berlin

To whom it may concern

Berlin, 31 March 2023

Extension of CE certificate validity

Herewith the management of the Eckert & Ziegler BEBIG GmbH confirms, that for the below named certificates, the extension of the validity date as defined in

MDR Art. 120 (according Regulation (EU) 2023/607, in effect since 20. Mar 2023)

applies:

Extended till 31. Dec 2028:
2180423CE02 **Radioactive Sources, Afterloading Systems, Applicators and Treatment Planning Systems for Brachytherapy**
Products of class IIa
Brachytherapy-applicators, Afterloading UMDNS 17-732 includes:
HDR-Afterloading accessories: Intracavitary applicators and accessories
HDR-Afterloading accessories: Oesophagus Set
HDR-Afterloading accessories: Universal applicators and accessories
Needles UMDNS 12-729 includes:
HDR-Afterloading accessories: Interstitial needles and catheters
HDR-Afterloading Accessories:
Interstitial Add-on Kits (needle guides, needle templates
Products of class IIb
Brachytherapy Radioactive Source UMDNS 17-518 includes:
Eye Applicators, Ruthenium-106
IsoSeed for temporary use on the eye, Iodine-125
Brachytherapy System, Afterloading device UMDNS 17-517 includes:
Afterloader for high dose rate, SagiNova
Treatment Planning Systems UMDNS 13-281 includes:
Treament Planning System SagiPlan
Treatment Planning System HDRplus

Managing Directors:
Dr. Harald Hasselmann
Dr. Dirk W. Becker

Berlin Office:
Amtsgericht Charlottenburg
Reg HRB 42949 B
VAT Reg. DE 137169788

Bank Account:
Commerzbank AG
IBAN DE29 1204 0000 0042 4648 00
BIC COBADEFFXXX

[redacted]

Eckert & Ziegler

Extended till 31. Dec 2027:
2180423CE03 **Implantable Seeds (I-125) and accessories**

Products:
- IsoSeed
- IsoCord
- IsoStrand

Accessories:
- IsoCord needle loader
- IsoStrand cutting fixture
- Brachytherapy implantation needles

Extended till 31. Dec 2027:
2180423DE06 **Implantable radioactive seeds and accessories for treatment of prostate cancer**

Products:
- IsoSeed I-125 (I25.S06, I25.S17 plus)
- IsoCord
- IsoStrand

Accessories:
- IsoCord needle loading station, with accessories
- IsoStrand cutting fixture
- Brachytherapy implantation needles

Berlin, 31. Mar 2023

[redacted]
Managing Director

[redacted]
Managing Director

Managing Directors:
Dr. Harald Hasselmann
Dr. Dirk W. Becker

Berlin Office:
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