

Certificate

The certification body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Healy GmbH
Schloss Kränzlin, Darritzer Strasse 6
16818 Kränzlin
Germany**

has introduced, applies and maintains a quality management system in the area of:

- Manufacture, final inspection and distribution of**
- **electro stimulation devices**
 - **devices for skin resistance measurement**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-11-03
Expiry date: 2021-12-12

Report No.: 7426PS03F
Procedure No.: QS – 7426
Certificate No.: 7426GB445201103A

Hamburg, 2020-11-03



MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems
certification body

EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Healy GmbH
Schloss Kränzlin, Darritzer Strasse 6
16818 Kränzlin
Germany**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-11-03

Expiry date: 2023-12-12

Report No.: 7426PS03

Process No.: QS – 7426

Certificate No.: 7426GB414201103A

Hamburg, 2020-11-03

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7426

Certificate No.: 7426GB414201103A

List of products / product categories included in the scope of certificate

Electro stimulation devices

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Healy GmbH
Schloss Kränzlin, Darritzer Strasse 6
16818 Kränzlin
Germany**

has introduced, applies and maintains a quality assurance system
**concerning the conformity of the medical devices with the metrological
requirements**

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-11-03

Expiry date: 2023-12-12

Report No.: 7426PS03F

Process No.: QS – 7426

Certificate No.: 7426GB416201103A

Hamburg, 2020-11-03

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7426

Certificate No.: 7426GB416201103A

List of products / product categories included in the scope of certificate

Devices for skin resistance measurement

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15



Frequencies for Life

EC-Declaration of Conformity

Within the meaning of Council Directive 93/42 EEC

of 14 June 1993 concerning medical device

This is a class IIa medical device.

Brand: Healy

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Company: Healy GmbH
Schloss Kränzlin
Darritzer Strasse 6
16818 Kränzlin - Germany



The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert**, Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of Healy GmbH.

Kränzlin, 07.01.2021

Place, date

CEO

CE 0482