

Certificate

The Certification Body

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

herewith confirms 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 compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 12 December 2020

Report No.: 7426IA01F
Process No.: QS - 7426
Certificate No.: 7426GB445180628

Hamburg, 28 June 2018

MEDCERT Certification Body
(Markus Bianchi)



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

EC-Certificate of Conformity

The Notified Body

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

herewith confirms 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:

Electro stimulation devices

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 12 December 2022

Report No.: 7426/A01F
Process No.: QS - 7426
Certificate No.: 7426GB414180628

Hamburg, 28 June 2018

MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482



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 confirms 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:

Devices for skin resistance measurement

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 12 December 2022

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Hamburg, 28 June 2018



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EC-Declaration of Conformity

Within the meaning of

Council Directive 93/42 EEC of 14 June 1993 concerning medical device

It is a medical device of Class IIa.

Brand: Healy

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

Firma: 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, 02.07.2018

Place, date

Healy GmbH
Schloss Kränzlin
Darritzer Str. 6
16818 Kränzlin, Germany



CEO

CE 0482