CERTIFICATE

EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

Kirchner & Wilhelm GmbH + Co. KG

Scope of certification:
Development, production and sales of medical devices for the General medicine

Certified location:
Eberhardstraße 56, 71679 Asperg, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50170-Z5-00.

This certificate is valid from 2015-02-17 to 2018-02-16

Certificate registration no.: 50170-11-00

DEKRA Certification GmbH
Stuttgart, 2015-02-12

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

CERTIFICATE

EN ISO 9001:2008

DEKRA Certification GmbH hereby certifies that the company

Kirchner & Wilhelm GmbH + Co. KG

Scope of certification:
Development, production and sales of medical devices for the General medicine

Certified location:
Eberhardstraße 56, 71679 Asperg, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50170-Z5-00.

This certificate is valid from 2015-02-17 to 2018-02-16

Certificate registration no.: 50170-56-02

DEKRA Certification GmbH
Stuttgart, 2015-02-12

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

Kirchner & Wilhelm GmbH + Co. KG

Eberhardstraße 56, 71679 Asperg, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50170-Z5-00, the decision dated 2015-02-12 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification:	1998-10-21	Date of the last recertification:	2015-02-17
This certificate is valid until:	2018-02-16	Certificate registration No.:	50170-16-03 Duplicate

DEKRA Certification GmbH
Stuttgart, 2015-02-12
Notified Body ID-number: 0124

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-295.10.02

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid

Annex to the EC Certificate 50170-16-03 dated 12.02.2015

Revision status: 1 Date: 26.06.2015 Page 1 of 1

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Devices/device categories included in the certificate

Class II a:

- SwiSto3 Iontophoresis Device
- SwiSto2 Iontophoresis Device

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex V

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

Kirchner & Wilhelm GmbH + Co. KG

Eberhardstraße 56, 71679 Asperg, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex V. The approval is based on the result of the re-certification audit report no. 50170-Z5-00, the decision dated 2015-02-12 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 2003-10-31

Date of the last recertification: 2015-02-17

This certificate is valid until: 2018-02-16

Certificate registration No.: 50170-17-04
Duplicate

DEKRA Certification GmbH

Stuttgart, 2015-02-12
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid

Annex to the EC Certificate 50170-17-04 dated 12.02.2015

Duplicate

Revision status: 0 Date: 17.02.2015 Page 1 of 1

Devices/device categories included in the certificate

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- sterile laryngoscope blades

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC Annex VI

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

Kirchner & Wilhelm GmbH + Co. KG

Eberhardstraße 56, 71679 Asperg, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex VI. The approval is based on the result of the re-certification audit report no. 50170-Z5-00, the decision dated 2015-02-12 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 2002-11-21

Date of the last recertification: 2015-02-17

This certificate is valid until: 2018-02-16

Certificate registration No.: 50170-18-04
Duplicate

DEKRA Certification GmbH

Stuttgart, 12.02.2015

Notified Body ID-number: 0124

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid

Annex to the Certificate 50170-18-04 dated 12.02.2015

Duplicate

Revision status: 0 Date: 17.02.2015

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Devices/device categories included in the certificate

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the manufacturing steps associated with product conformity and metrological requirements.

- KaWe MASTERMED ® A1
- KaWe MASTERMED ® A1+
- KaWe MASTERMED ® T5
- KaWe MASTERMED ® C

Class II a:

- KaWe MASTERMED ® MF5