

CERTIFICATE



EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

KaWeCo GmbH

Scope of certification:

Development, manufacturing and distribution of medical products for general medical purpose

Certified location:

Gerlinger Straße 36-38, 71254 Ditzingen, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50350-Z5-00.

This certificate is valid from 2016-07-30 to 2019-07-29

Certificate registration no.: 50350-11-01

A handwritten signature in black ink, appearing to read 'Thiel'.



DEKRA Certification GmbH Stuttgart; 2016-07-25

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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

KaWeCo GmbH

Gerlinger Straße 36-38, 71254 Ditzingen, 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. 50350-Z5-00, the decision dated 2016-07-25 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-07-30 to 2019-07-29

Certificate registration No.: 50350-16-03



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

DEKRA Certification GmbH Stuttgart; 2016-07-25
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50350-16-03 dated 2016-07-25

Revision status: 1

Date: 2016-11-28

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Devices/device categories included in the certificate

Class II a:

- Breast pumps, electrical
- mamivac suction kits
- mamivac nipple shields

