EC CERTIFICATE

Number: 96395CE02

Production Quality Assurance

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

Manufacturer:

Koninklijke Utermöhlen N.V.

De Overweg 1
8471 ZA Wolvega
The Netherlands

For the product category(ies)

Cryotherapy devices for removal of warts caused by Human Papilloma Virus and Mollusca Contagiosa, skin tags and other skin lesions

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 96395CN, initially dated 1 October 1999
Addendum, initially dated 28 April 2014

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 the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
The necessary information related to the quality assurance 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: 1 October 2023
Issued for the first time: 17 March 2008
Reissued: 30 November 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

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ADDENDUM

Belonging to certificate: 96395CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Cryotherapy devices for removal of warts caused by Human Papilloma Virus and Mollusca Contagiosa, skin tags and other skin lesions

Issued to:

Koninklijke Utermöhlen N.V.
De Overweg 1
8471 ZA Wolvega
The Netherlands

This certificate covers the following product(s):

Cryotherapy devices intended for removal and treatment of the following indications:
- Human Papilloma Virus caused warts
- Human Mollusca Contagiosa caused warts (MC lesions)
- Acrochordon (Skin Tags)
- Genital warts
- Verruca (Plantaris, Vulgaris, Plana)
- Seborrheic Keratosis (SK's)
- Actinic Keratosis (AKs), facial and other body parts
- Lentigo's, facial and other body parts

Initial date: 28 April 2014

DEKRA Certification B.V.

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