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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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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.

B.T.M. Holtus
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DEKRA

Koninklijke Utermöhlen N.V.
Also trading as Royal Utermöhlen
De Overweg 1
8471 ZA Wolvega
P.O. Box 3
8470 AA Wolvega
The Netherlands

Your ref.
Our ref. MED/23-235
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 1 September 2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Koninklijke Utermöhlen N.V.
Also trading as Royal Utermöhlen
De Overweg 1
8471 ZA Wolvega
P.O. Box 3
8470 AA Wolvega
The Netherlands

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement

concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Alfred van der Meer
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HeltiQ Wart Freezer product family	Class IIa	N/A	96395CE02
HeltiQ Skin Tags product family	Class IIa	N/A	96395CE02
Utermöhlen Cryo Pro product Family	Class IIa	N/A	96395CE02
HeltiQ Tick Away product family	Class IIa	N/A	96395CE05

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023/09/01	96395CN25.1	Initial issue