

# EC CERTIFICATE

Number: 96395CE03

## 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)

**Instant cooling device for cooling by heat exchange of the human body for pain relief**

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

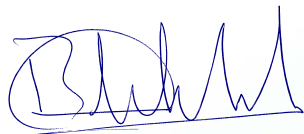
Documents, that form the basis of this certificate:

**Certification Notice 96395CN, initially dated 1 October 1999**  
**Addendum, initially dated 2 November 2011**

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: 2 November 2011  
Reissued: 30 November 2018

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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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: 96395CE03

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Instant cooling device for cooling by heat exchange of the human body for pain relief

Issued to:

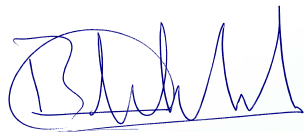
**Koninklijke Utermöhlen N.V.**  
De Overweg 1  
8471 ZA Wolvega  
The Netherlands

This certificate covers the following product(s):

- Instant koud kompres

Initial date: 2 November 2011

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt  
Certification Manager

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T +31 88 96 83000 F +31 88 96 83100 [www.dekra-certification.com](http://www.dekra-certification.com) Company registration 09085396