Utermöhlen Since 1880	**MANUFACTURER'S DECLARATION OF CONFORMITY CRYO PROFESSIONAL**	Document	DOC3
		Rev level	8
		Date effective:	June 16, 21
		Page	1 / 2

Koninklijke Utermöhlen N.V., also trading under the brand name HeltiQ, SRN: Manufacturer NL-MF-000004873, Overweg 1, Wolvega Netherlands,

This EU declaration of conformity is issued under the sole responsibility of **Koninklijke Utermöhlen N.V.**

Medical device Schedule*:*

Product Name	**Accessories packaged with the product**	**Ref**	
European & International product only: 170 ml			
Utermöhlen Cryo Professional	60 x 2mm foam-sticks	UTM0170	8717484005811
Utermöhlen Cryo Professional	50 x 5 mm foam-sticks	UTM0169	8717484005798
Utermöhlen Cryo Professional	60 x mixed: 30 x 2mm & 30 x 5mm foam-sticks	UTM0171	8717484005835
European & International product only: 80ml			
Utermöhlen Cryo Professional	60 x 2mm foam-sticks	UTM0001	Not yet assigned
Utermöhlen Cryo Professional	50 x 5 mm foam-sticks	UTM0050	Not yet assigned
Utermöhlen Cryo Professional	60 x mixed: 30 x 2mm & 30 x 5mm foam-sticks	UTM0100	Not yet assigned

Product and trade name: Utermöhlen Cryo Professional

Product codes:

GMDN Code: 11067;

Term: General cryosurgical system, mechanical:
Definition: An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal. The systemtypically includes a mechanical regulator to control the flow of cryogen, contained in an attached cylinder, and the probe(s) to apply the cold. The system is used across clinical specialties (e.g., general surgery, dermatology, oral surgery, gynaecology, urology, ENT, proctology, oncology) to remove malignant or abnormal benign tissues.

CDN: Z120102: Cryosurgical units

Intended purpose: The product is indicated for use for the removal of various skin lesions, including but not limited to, verrucae (e.g., common and plantar warts), molluscum contagiosum (i.e., MC lesions or chickenpox), cutaneous papilloma or acrochordon (i.e., skin tags). Apply the foam-stick on the skin lesion for between 20 to 40 seconds depending on the lesion to be treated. The treat-ment can be repeated at 2-week intervals.

Risk class: Class IIa; Rule 11 (i.e. active medical devices to administer other substances to the body).

We, **Koninklijke Utermöhlen N.V., SRN: Manufacturer NL-MF-000004873, Overweg 1, Wolvega Netherlands,** hereby declare that in view of article 120 of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017 on medical devices, the medical device herein specified conforms to the essential requirements of DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

The name and identification number of the notified body

Dekra certification BV identification number 0344

Description of the conformity assessment procedure performed

For Class II-a medical device, conformity assessment is based on Annex VII (technical documentation) and Annex V (production quality assurance) of of Directive 93/42/EEC . The product is approved outside the European Union, in the US, Australia, Asia, etc., through pre-market applications.

Identification of the certificate or certificates issued
Our notified body, Dekra (0344), has evaluated our technical documentation and design file and issued an *CE Certificate* for Annex VII with V (Nr: 96395CE02); and an ISO 13485:2016 quality system certificate (Nr 49211) and ISO 13485:2016 MDSAP (Nr 2228630).

Additional information:

Scope of Application: For each medical device herein specified, we further declare that:

- To keep an up-to-date, effective and approved quality management system in place at our manufacturing facility;
- To institute and keep an up to date procedure for review of experience gained from our device in post marketing surveillance phase including where and when appropriate post-market surveillance (PMS) and post-market clinical follow up (PMCF) concerning performance and efficacy of the product;
- To keep a complaints file and comply with prevailing medical device vigilance requirements and appropriately and timely report any anomalies which may arise with the device;
- To ensure that any clinical trials which we conduct will be conform Annex X and meet all relevant GCP requirements for medical devices (national, international and ISO 14155);
- To ensure any subcontractors used for any activity concerning the product are appropriately controlled and inspected under the quality system requirements;
- That the appropriate technical documentation has been prepared in accordance with Annex VII with Annex V of Directive 93/42/EEC as amended and is retained at our facility in Wolvega;
- That appropriate records of changes or revisions of the product's technical documentation as a result of changes to the design or production of the product, as well as changes or revisions to the design of the product or production processes are documented;
- That substantial changes which affect safety, efficacy, quality or performance of processes, components and quality are notified to the notified body in advance of their implementation;
- To keep this Declaration and the product's technical documentation specified in Annex II for at least 10 years from the last date of product manufacture.

This Declaration is valid for each medical device herein specified as manufactured from date this document is signed.

Signature:

Name: M. Pereboom **Position**: Managing Director **Date**: 16 June 2021