Utermöhlen Since 1880	**MANUFACTURER'S DECLARATION OF CONFORMITY CRYO PROFESSIONAL**	Document	DOC3
		Rev level	5
		Date effective:	16 Jan 2019
		Page	1 / 2

We, **Koninklijke Utermöhlen NV., De Overweg 1, 8471ZA, Wolvega, The Netherlands,** hereby declare that the medical device herein specified conforms to the essential requirements of Directive 93/42/EEC as amended by Directive 2007/47/EC of 5 September 2007 and hereby make this declaration in compliance with Annex VII with Annex V of Directive 93/42/EEC as henceforth amended.

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

Product Family: Products covered by this Declaration are active medical devices, Cryosurgical products used for professional use to treat skin lesions.

Medical device: Utermöhlen Cryo Professional

Medical device Schedule:

Product Name	Accessories packaged with the product	Ref
European & International product only		
Utermöhlen Cryo Professional	60 x 2mm foam-sticks	UTM0170
Utermöhlen Cryo Professional	50 x 5 mm foam-sticks	UTM0169
Utermöhlen Cryo Professional	60 x mixed: 30 x 2mm foam-sticks & 30 x 5mm foam-sticks	UTM0171
China Product only		
Utermöhlen Cryo Professional	60 x 2mm foam-sticks	UTM2170
Utermöhlen Cryo Professional	50 x 5 mm foam-sticks	UTM1169
Utermöhlen Cryo Professional	60 x mixed: 30x 2mm foam-sticks & 30 x 5mm foam-sticks	UTM3171
Utermöhlen Cryo Professional	50 x mixed: 25 x 2mm foam-sticks & 25 x 5mm foam-sticks	UTM4172

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.

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

- To keep at up-to-date, effective and approved quality system in place at our manufacturing facility;
- To institute and keep up to date a systematic procedure for review of experience gained from our device in post marketing surveillance phase including where and when appropriate post-market clinical follow up (PMCFU) 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 the 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 5 years from the last date of product manufacture.

Our notified body, Dekra (0344), has evaluated our technical documentation and design file and issued an *CE Certificate* for Annex VII with V (Nr: 96395CN); and an ISO 13485:2012 quality system certificate (Nr 49211) and an ISO 13485:2003 for Canada (Nr 2130424).

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 Jan 2019