Utermöhlen
Since 1880

Manufacturer's Declaration of Conformity

We, **Koninklijke Utermohlen, Overweg 1, Wolvega 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 in combination with Annex V of Directive 93/42/EEC as henceforth amended.

Classification: The medical device covered by this Declaration is Class IIa medical device under Rule 9 (i.e. active therapeutic devices intended to administer or exchange energy).

Product Family: Products covered by this Declaration are active medical devices, **Cryosurgical products** used in wound management.

Medical device: Utermöhlen Cryo Professional

Medical device Schedule: The composition of the device is listed on the appended medical device schedule.

GMDN Code: The code for the product is **44724, Cryogenic spray, cutaneous**
UMDNS Code: The code for the product is **18051, Cyrosurgical unit**

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 in combination 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 Certification BV (0344), has evaluated our technical documentation and design file and issued an *CE Certificate* for Annex VII in combination 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: D.T van der Vat **Position**: CEO **Date**: 2016-01-20

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Medical device schedule

In this device schedule, the details of the Cryo Pro product is supplied to the professional market. The medical device schedule is part of the Declaration of Conformity and can be updated as product sizes or order numbers change.

Product Name	**Accessories packaged with the product**	Unique device identifier / Ref
Utermöhlen Cryo Professional	50 x 5 mm foam-sticks	**UTM0169**
Utermöhlen Cryo Professional	60 x 2 mm foam-sticks	**UTM0170**
Utermöhlen Cryo Professional	30 x 2 mm foam-sticks & 30 x 5 mm foam-sticks	**UTM0171**