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: Askina Skin Freeze

Medical device Schedule:

Product Name	Accessories packaged with the product	Ref UTM	Ref Askina
Askina Skin freeze Small	60 x 2mm foam-sticks	UTM0175	9380702
Askina Skin freeze Medium	50 x 5 mm foam-sticks	UTM0176	9380703
Askina Skin freeze Mix	30 x 2mm foam-sticks & 30 x 5mm foam-sticks	UTM0177	9380704

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 13485:2016 quality system certificate (Nr 49211) and ISO 13485:2016 MDSAP (Nr 2228630).

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

Signature:
Name: P. Bandell **Position**: Managing Director **Date**: 21 July 20

Effective