Nasaleze® ALLERGY WITH MINT
natural allergy prevention

WORLDWIDE AUTHORISED REPRESENTATIVE IN EUROPE

Kisska International Ltd.

Bethel Hall, Morton Lane, East Morton, Keighley BD20 5UE UK

EC DECLARATION OF CONFORMITY

The EC Directives covered by this Declaration

Council Directive 93/42/EEC of 14th June 1993 concerning Medical Devices as amended by Directive 98/79/EC

The products covered by this Declaration

The Nasaleze™ Natural Hayfever & Allergy Prevention Device

The Basis on which Conformity is Declared

Class of the device as defined in the Directive Annex IX is Class 1

The product identified above complies with the essential requirements of the Medical Devices Directive

The following Normative European Standards have been used to meet the Essential Requirements of the Directive:

EN ISO 14971:2009 Medical Devices. Application of risk management to medical devices

EN 980:2008 Symbols for use in the labelling of medical devices

EN ISO 10993-1: 2009 Biological evaluation of medical devices. Evaluation and testing within a risk management process.

EN 1041:2008 Information supplied by the manufacture of medical devices

EN ISO 13485:2003 Medical Devices. Quality management systems. Requirements for regulatory purposes.

The technical documentation required to demonstrate that the requirements of the Medical Devices Directive has been compiled by the signatory below and is available for inspection by the relevant enforcement authorities.

CE Mark - the device registration has been submitted to the UK Medical and Healthcare Products Regulatory Agency (formerly the Medical Devices Agency) on Form RG2 and has been duly registered based on that declaration under the UK MDA reference number CA007190 date 23 January 2002.

I hereby certify that the products described above comply with the essential requirements of the Medical Devices Directive 93/42/EEC of 14th June 1993:

Signed: M. James · Date: 22nd October 2010

Name: Mike James

Authority: Director

(Technical Director or other person "employed to bind the company")

I CERTIFY THIS IS THE ORIGINAL DOCUMENT PRODUCED TO ME AT BRADFORD ON 26-10-10

NOTARY PUBLIC

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The attention of the specifier, purchaser, or user is drawn to the special precautions and limitations which are included in the User Documentation for the product and which are also available from the Company on request.

NOTARY PUBLIC KEITH I. ENDERBY BRADFORD