MANUFACTURER'S EC DECLARATION OF CONFORMITY

We, **OraSure Technologies, Inc., 220 East First Street, Bethlehem, Pennsylvania 18015, United States**, hereby declare that the Class IIa medical devices specified below complies with Directive 93/42/EEC concerning medical devices and its relevant transposition into all national laws of the member states into which we place the devices, and make this declaration in compliance with Annex 2 of the Directive.

Products covered by this declaration fall in the product family **Cryosurgical Products** and include the following variants of the Histofreezer® Portable Cryosurgical System:

Variants:

1001-0411 1001-0408	H-602	60 Application Kit w/ 60 - 2mm Buds
1001-0410 1001-0409	H-505	50 Application Kit w/ 52 - 5mm Buds
1001-0413 1001-0412	H60	60 Application Kit w/ 24 - 2mm Buds and 36 - 5mm Buds
1001-0341	H30M	30 Application Kit w/ 15 - 2mm Buds and 15 - 5mm Buds

Sample Kit

H-105	H-105	5 Application w/ 2 - 2mm Buds and 3 - 5mm Buds – Sample Kit

The foam applicators (buds) are manufactured to our specifications in Thailand by Foamtec International. The filled canisters are manufactured to our specification in the Netherlands by Royal Sanders. Kit assembly and finished product testing is conducted to our specification in the USA by F.M. Howell and Company.

The products covered by this declaration are CE-marked under a conformity assessment process defined by Annex II, which has been inspected by our Notified Body, Presafe Denmark A/S (formerly DGM Denmark A/S) supported by certificate DGM-605.

We furthermore, undertake to maintain an up-to-date compliant quality system, keep a complaints file, to comply with prevailing medical device vigilance requirements, to institute and keep up-to-date a systematic procedure for review experience gained from devices in post marketing surveillance phase, to implement corrective actions, and to keep this Declaration and the product's technical documentation specified in Annex 2 for at least 5 years from the last date of product manufacture.

A copy of the technical documentation for the herein referenced products is retained by our authorized representative, Qarad b.v.b.a., Cipalstraat 3, B-2440 GEEL, Belgium.

Signed/Date: Tiffany Miller 30 May 2018
Position: Director, Regulatory Affairs