EC Certificate Full Quality Assurance System: Certificate US96/8856

The management system of

Brymill Cryogenic Systems

105 Windermere Avenue, Ellington, CT, 06029, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Cryosurgery Guns for the delivery of Liquid Nitrogen in the treatment of Cutaneous Skin Lesions.

Cryosurgery Closed Probes, Cryochambers, Straight Sprays, Bent Sprays, Straight Spray Extensions, Bent Spray Extensions Apertures - Accessories to the Cryosurgery Guns to control the output of the Liquid Nitrogen. Cryochambers – accessories to the cryosurgery guns to allow surgical destruction of tissue up to 3 cm deep by causing LN2 to pol continuously over deep lesions.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 12 September 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 March 2022
Issue 16. Certified since 30 November 1996

Certification is based on reports numbered WW/MC 06139

Authorised by

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