

Declaration of Conformity

Application of Council Directive(s): Medical Device Directive 93/42/EEC

Standards to which Conformity is Declared: EN ISO 13485:2003, EN ISO 14971:2007, EN ISO 11737-1:2006, EN ISO 10993:2003, ISO 15223:2007, EN 1041

Manufacturer's Name: Vycor Medical Inc

Manufacturer's Address: 3651 FAU Blvd, Ste 300, Boca Raton, FL USA 33431

Community Representative: MediMark Europe, 11, rue Emile Zola, BP 2332
38033 Grenoble Cedex 2, France

Notified Body: AMTAC Certification Services Limited, Davy Avenue,
Knowlhill, Milton Keynes MK5 8NL, United Kingdom

Type of Equipment: Vycor ViewSite Surgical Access System

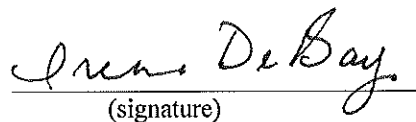
Device Classification per MDD 93/42/EEC: Class III, Rule 7

Model Numbers: TC120803, TC120805, TC120807, TC171103,
TC171105, TC171107, TC211503, TC211505,
TC211507, TC282003, TC282005, TC282007,
EC341403, EC341405, EC341407

Serial Numbers: N/A

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive (s) and Standard (s).

Place: Boca Raton, FL USA


(signature)

Date: June 24, 2011

Irene DeBay
(full name)

Quality Assurance /Regulatory Affairs
(Position)

Rev H



Targeting Solutions in Neurosurgery