Declaration of Conformity

Application of Council Directive(s):	Medical Device Directive 93/42/EEC
Conformity assessment route:	Annex II
Manufacturer's Name:	Vycor Medical, Inc.
Manufacturer's Address:	951 Broken Sound Parkway, Suite 320, Boca Raton, FL 33487, USA
Community Representative:	MediMark Europe, 11, rue Emile Zola, BP 2332 38033 Grenoble Cedex 2, France
Notified Body:	DNV Product Assurance AS. Veritasveien 1, 1363 Oslo, Norway **NB Number: 2460**
CE Certificates:	Certificate Number: 10000360569-PA-NA-USA Rev.1 Initial Certification Date: 23rd April 2020 Certificate Number: 10000309598-PA-NA-USA Rev.1 Initial Certification Date: 23rd April 2020
Type of Equipment:	Vycor ViewSite Brain Access System™
Device Classification per MDD 93/42/EEC:	Class III, Rule 7
Model Numbers:	TC060405, TC060407, TC120803, TC120805, TC120807, TC171103, TC171105, TC171107, TC211503, TC211505, TC211507, TC282003, TC282005, TC282007, TC120803AC, TC120805AC, TC120807AC, TC171103AC, TC171105AC, TC171107AC, TC211503AC, TC211505AC, TC211507AC, TC282003AC, TC282005AC, TC282007AC
Serial Numbers:	N/A

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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place: Boca Raton, FL USA

(Signature)

Date: April 21, 2021

David M, Cantor
(Full name)
President
(Position)