



EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 10000309598-PA-NA-USA Rev 1 Project No.: PRJC-595254-2019-PRC-USA

Valid Until: 27 May 2024

This is to certify that the quality system of:

Vycor Medical, Inc.

951 Broken Sound Parkway, Suite 320, Boca Raton, Florida 33487, USA

For design, production and final product inspection/testing of:

VIEWSITE BRAIN ACCESS SYSTEM (VBAS)

Has been assessed with respect to:

the conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 April 2021

For the issuing office:
**Notified Body 2460
DNV Product Assurance AS**



Palani Damodharan
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f3, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	23 April 2020
1.0	Scope extension to add VBAS models with alignment clips (in bold)	20 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Vycor ViewSite Surgical Access System (Non-active self-retaining retractor system for brain tissue)	Vycor ViewSite Surgical Access System (VBAS) Model# 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	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 10000360569-PA-NA-USA

Sites covered by this certificate

Site Name	Address
Vycor Medical, Inc. (main site)	951 Broken Sound Parkway, Suite 320, Boca Raton, Florida 33487, USA
Life Science Outsourcing, Inc. (Main sub-contract manufacturer)	830 Challenger Street, Brea, California 92821, USA
Accent Plastics, Inc. (Injection moulded part sub-contract manufacturer)	1925 Elise Circle, Corona, California 92879, USA

EU Representative

MediMark Europe Sarl,
11 rue Emile ZOLA, B.P. 2332, 38033 GRENOBLE CEDEX 2, FRANCE

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate