



DNV

EC Design Examination Certificate

Certificate No.: 10000360569-PA-NA-USA Rev 1 Project No.: PRJC-595254-2019-PRC-USA

Valid Until: 27 May 2024

This is to certify that:

VIEWSITE BRAIN ACCESS SYSTEM (VBAS)

Manufactured by:

Vycor Medical, Inc.

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

Has been assessed with respect to:

examination of the design of the product as described in Annex II section 4 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-f4, 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 (AC) (in Bold)	20 April 2021

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
<p>Vycor ViewSite Surgical Access System (Non-active self-retaining retractor system for brain tissue)</p> <p>Model#TC060405, TC060407, TC120803, TC120805, TC120807, TC171103, TC171105, TC171107, TC211503, TC211505, TC211507, TC282003, TC282005, TC282007,</p> <p>TC120803AC, TC120805AC, TC120807AC, TC171103AC, TC171105AC, TC171107AC, TC211503AC, TC211505AC, TC211507AC, TC282003AC, TC282005AC, TC282007AC</p>	III	--
<p>Short description of the Medical Device:</p> <p>Vycor ViewSite Surgical Access System (VBAS) is a non-active instrument (self-retaining retractor system for brain tissue). It is intended to provide for access and allow for visualization of the surgical field during brain and spine surgery. This is a family of retractor and brain access devices of varying shapes and sizes designed for providing diagnostic and surgical access to various portions of the brain and spine. It has been designed to serve as a self-retaining retractor system for brain tissue.</p> <p>There is also an Alignment Clip (AC) included separately in the packaging of some models with the AC suffix that may be optionally attached to aid in the centring of third-party instrumentation, specifically navigational and image guided system (“IGS”) pointers or probes (“pointer”).</p> <p>Details of available models are listed below.</p>		

Without alignment clip included in the packaging:

Model	Length	Major Distal Port Diameter	Minor Distal Port Diameter	UDI/GTIN/DI numbers
TC060405	5cm	6mm	4mm	00859261006005
TC060407	7cm	6mm	4mm	00859261006012
TC120803	3 cm	12 mm	8 mm	00859261006029
TC120805	5 cm	12 mm	8 mm	00859261006036
TC120807	7 cm	12 mm	8 mm	00859261006043
TC171103	3 cm	17 mm	11 mm	00859261006050
TC171105	5 cm	17 mm	11 mm	00859261006067
TC171107	7 cm	17 mm	11 mm	00859261006074
TC211503	3 cm	21 mm	15 mm	00859261006081
TC211505	5 cm	21 mm	15 mm	00859261006098
TC211507	7 cm	21 mm	15 mm	00859261006104
TC282003	3 cm	28 mm	20 mm	00859261006111
TC282005	5 cm	28 mm	20 mm	00859261006128
TC282007	7 cm	28 mm	20 mm	00859261006135

With alignment clip included in the packaging:

Model	Length	Major Distal Port Dia.	Minor Distal Port Dia.	Alignment Clip (AC) Component Size	UDI/GTIN/DI numbers
TC120803AC	3 cm	12 mm	8 mm	27 mm	00859261006258
TC120805AC	5 cm	12 mm	8 mm	27 mm	00859261006241
TC120807AC	7 cm	12 mm	8 mm	27 mm	00859261006234
TC171103AC	3 cm	17 mm	11 mm	32 mm	00859261006227

TC171105AC	5 cm	17 mm	11 mm	32 mm	00859261006210
TC171107AC	7 cm	17 mm	11 mm	32 mm	00859261006203
TC211503AC	3 cm	21 mm	15 mm	36 mm	00859261006197
TC211505AC	5 cm	21 mm	15 mm	36 mm	00859261006180
TC211507AC	7 cm	21 mm	15 mm	36 mm	00859261006173
TC282003AC	3 cm	28 mm	20 mm	43 mm	00859261006166
TC282005AC	5 cm	28 mm	20 mm	43 mm	00859261006159
TC282007AC	7 cm	28 mm	20 mm	43 mm	00859261006142



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 change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System. 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