



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-064/A

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class III,

Rapid Exchange PTCA Balloon Catheter
Brand Name: Vas Track
(for detailed list refer to Annex; pages 1 to 2)

manufactured by company

Vasmed Technologies Ltd FZC
Facility No. 116, Fujairah Free Zone, Fujairah, United Arab Emirates

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT_68 and the Final protocol No. 310421/2019, 310421A/2021.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended, Annex II (4) is required.




Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on May 25th, 2021
Version A) supersedes the EC Certificate No. 2019-MDD/QS-064 issued on October 9th, 2019

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	October 9 th , 2019	310421	First issue of the Certificate
A	May 25 th , 2021	310421A	The addition of new sizes



ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-064/A

issued for the company

Vasmed Technologies Ltd FZC
Facility No. 116, Fujairah Free Zone, Fujairah, United Arab Emirates

List of medical devices covered by the EC Certificate:

Brand Name: Vas Track

MODEL NUMBER	SIZE (Dia. x Length)	MODEL NUMBER	SIZE (Dia. x Length)
VM-VT-100-10	1.00 X 10 MM	VM- VTII -200-32	2.00 X 32 MM
VM-VT-100-15	1.00 X 15 MM	VM- VTII -200-34	2.00 X 34 MM
VM-VT-100-20	1.00 X 20 MM	VM- VTII -200-36	2.00 X 36 MM
VM-VT-100-25	1.00 X 25 MM	VM- VTII -200-38	2.00 X 38 MM
VM-VT-100-30	1.00 X 30 MM	VM- VTII -200-42	2.00 X 42 MM
VM-VT-100-32	1.00 X 32 MM	VM-VT-250-10	2.50 X 10 MM
VM-VT-100-34	1.00 X 34 MM	VM-VT-250-15	2.50 X 15 MM
VM-VT-100-36	1.00 X 36 MM	VM-VT-250-20	2.50 X 20 MM
VM-VT-100-38	1.00 X 38 MM	VM-VT-250-25	2.50 X 25 MM
VM- VT-100-42	1.00 X 42 MM	VM-VT-250-30	2.50 X 30 MM
VM-VTII-100-10	1.00 X 10 MM	VM-VT-250-32	2.50 X 32 MM
VM- VTII -100-15	1.00 X 15 MM	VM-VT-250-34	2.50 X 34 MM
VM- VTII -100-20	1.00 X 20 MM	VM-VT-250-36	2.50 X 36 MM
VM- VTII -100-25	1.00 X 25 MM	VM-VT-250-38	2.50 X 38 MM
VM- VTII -100-30	1.00 X 30 MM	VM- VT-250-42	2.50 X 42 MM
VM- VTII -100-32	1.00 X 32 MM	VM-VT-275-10	2.75 X 10 MM
VM- VTII -100-34	1.00 X 34 MM	VM-VT-275-15	2.75 X 15 MM
VM- VTII -100-36	1.00 X 36 MM	VM-VT-275-20	2.75 X 20 MM
VM- VTII -100-38	1.00 X 38 MM	VM-VT-275-25	2.75 X 25 MM
VM- VTII -100-42	1.00 X 42 MM	VM-VT-275-30	2.75 X 30 MM
VM-VT-125-10	1.25 X 10 MM	VM-VT-275-32	2.75 X 32 MM
VM-VT-125-15	1.25 X 15 MM	VM-VT-275-34	2.75 X 34 MM
VM-VT-125-20	1.25 X 20 MM	VM-VT-275-36	2.75 X 36 MM
VM-VT-125-25	1.25 X 25 MM	VM-VT-275-38	2.75 X 38 MM
VM-VT-125-30	1.25 X 30 MM	VM- VT-275-42	2.75 X 42 MM
VM-VT-125-32	1.25 X 32 MM	VM-VT-300-10	3.00 X 10 MM
VM-VT-125-34	1.25 X 34 MM	VM-VT-300-15	3.00 X 15 MM
VM-VT-125-36	1.25 X 36 MM	VM-VT-300-20	3.00 X 20 MM
VM-VT-125-38	1.25 X 38 MM	VM-VT-300-25	3.00 X 25 MM
VM- VT-125-42	1.25 X 42 MM	VM-VT-300-30	3.00 X 30 MM
VM-VTII-125-10	1.25 X 10 MM	VM-VT-300-32	3.00 X 32 MM
VM- VTII -125-15	1.25 X 15 MM	VM-VT-300-34	3.00 X 34 MM
VM- VTII -125-20	1.25 X 20 MM	VM-VT-300-36	3.00 X 36 MM
VM- VTII -125-25	1.25 X 25 MM	VM-VT-300-38	3.00 X 38 MM
VM- VTII -125-30	1.25 X 30 MM	VM- VT-300-42	3.00 X 42 MM
VM- VTII -125-32	1.25 X 32 MM	VM-VT-325-10	3.25 X 10 MM
VM- VTII -125-34	1.25 X 34 MM	VM-VT-325-15	3.25 X 15 MM

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At Bratislava, on May 25th, 2021
Valid until May 26th, 2024



Dr. Katarina Tomín Srdošová
Responsible to act on behalf of NB 2265



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issued for the company

Vasmed Technologies Ltd FZC
Facility No. 116, Fujairah Free Zone, Fujairah, United Arab Emirates

List of medical devices covered by the EC Certificate:

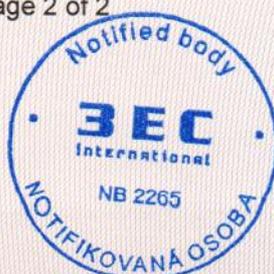
Brand Name: Vas Track

MODEL NUMBER	SIZE (Dia. x Length)	MODEL NUMBER	SIZE (Dia. x Length)
VM-VTII-125-36	1.25 X 36 MM	VM-VT-325-20	3.25 X 20 MM
VM-VTII-125-38	1.25 X 38 MM	VM-VT-325-25	3.25 X 25 MM
VM-VTII-125-42	1.25 X 42 MM	VM-VT-325-30	3.25 X 30 MM
VM-VT-150-10	1.50 X 10 MM	VM-VT-325-32	3.25 X 32 MM
VM-VT-150-15	1.50 X 15 MM	VM-VT-325-34	3.25 X 34 MM
VM-VT-150-20	1.50 X 20 MM	VM-VT-325-36	3.25 X 36 MM
VM-VT-150-25	1.50 X 25 MM	VM-VT-325-38	3.25 X 38 MM
VM-VT-150-30	1.50 X 30 MM	VM-VT-325-42	3.25 X 42 MM
VM-VT-150-32	1.50 X 32 MM	VM-VT-350-10	3.50 X 10 MM
VM-VT-150-34	1.50 X 34 MM	VM-VT-350-15	3.50 X 15 MM
VM-VT-150-36	1.50 X 36 MM	VM-VT-350-20	3.50 X 20 MM
VM-VT-150-38	1.50 X 38 MM	VM-VT-350-25	3.50 X 25 MM
VM-VT-150-42	1.50 X 42 MM	VM-VT-350-30	3.50 X 30 MM
VM-VTII-150-10	1.50 X 10 MM	VM-VT-350-32	3.50 X 32 MM
VM-VTII-150-15	1.50 X 15 MM	VM-VT-350-34	3.50 X 34 MM
VM-VTII-150-20	1.50 X 20 MM	VM-VT-350-36	3.50 X 36 MM
VM-VTII-150-25	1.50 X 25 MM	VM-VT-350-38	3.50 X 38 MM
VM-VTII-150-30	1.50 X 30 MM	VM-VT-350-42	3.50 X 42 MM
VM-VTII-150-32	1.50 X 32 MM	VM-VT-375-10	3.75 X 10 MM
VM-VTII-150-34	1.50 X 34 MM	VM-VT-375-15	3.75 X 15 MM
VM-VTII-150-36	1.50 X 36 MM	VM-VT-375-20	3.75 X 20 MM
VM-VTII-150-38	1.50 X 38 MM	VM-VT-375-25	3.75 X 25 MM
VM-VTII-150-42	1.50 X 42 MM	VM-VT-375-30	3.75 X 30 MM
VM-VT-200-10	2.00 X 10 MM	VM-VT-375-32	3.75 X 32 MM
VM-VT-200-15	2.00 X 15 MM	VM-VT-375-34	3.75 X 34 MM
VM-VT-200-20	2.00 X 20 MM	VM-VT-375-36	3.75 X 36 MM
VM-VT-200-25	2.00 X 25 MM	VM-VT-375-38	3.75 X 38 MM
VM-VT-200-30	2.00 X 30 MM	VM-VT-375-42	3.75 X 42 MM
VM-VT-200-32	2.00 X 32 MM	VM-VT-400-10	4.00 X 10 MM
VM-VT-200-34	2.00 X 34 MM	VM-VT-400-15	4.00 X 15 MM
VM-VT-200-36	2.00 X 36 MM	VM-VT-400-20	4.00 X 20 MM
VM-VT-200-38	2.00 X 38 MM	VM-VT-400-25	4.00 X 25 MM
VM-VT-200-42	2.00 X 42 MM	VM-VT-400-30	4.00 X 30 MM
VM-VTII-200-10	2.00 X 10 MM	VM-VT-400-32	4.00 X 32 MM
VM-VTII-200-15	2.00 X 15 MM	VM-VT-400-34	4.00 X 34 MM
VM-VTII-200-20	2.00 X 20 MM	VM-VT-400-36	4.00 X 36 MM
VM-VTII-200-25	2.00 X 25 MM	VM-VT-400-38	4.00 X 38 MM
VM-VTII-200-30	2.00 X 30 MM	VM-VT-400-42	4.00 X 42 MM

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[Signature]
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