



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

# EC DESIGN-EXAMINATION CERTIFICATE

## No. 2019-MDD/DE-061/A

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

**High Pressure Non Compliant Rapid Exchange PTCA Balloon Catheter**  
**Brand Name: High Track**

(for detailed list refer to Annex; pages 1 to 1)

manufactured by company

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

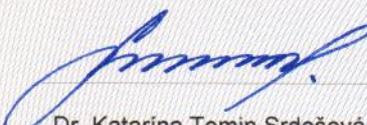
conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC as amended on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC as amended taking into account intended purpose of the device.

The Notified Body No. 2265 has performed a design-examination of the device according to Annex II.4 of the Directive 93/42/EEC as amended. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310421/2019, 310421A/2021.

*This certificate is issued under the following conditions:*

It applies only to the design of the above referenced model of the medical device and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all medical devices of the respective model conform to the type whose design has been approved by this certificate. The certificate remains valid until the approved design is changed but till May 26<sup>th</sup>, 2024 at the latest. This EC design-examination certificate is complementary to an EC Certificate, approving the manufacturer's quality system according to the Directive 93/42/EEC as amended, Annex II (excluding 4).



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

At Bratislava, on May 25<sup>th</sup>, 2021

Version A) supersedes the EC Design-Examination Certificate No. 2019-MDD/DE-061 issued on October 9<sup>th</sup>, 2019

Certificate history:

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



# ANNEX TO EC DESIGN-EXAMINATION CERTIFICATE No. 2019-MDD/DE-061/A

issued for the company

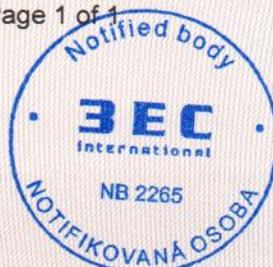
**Vasmed Technologies Ltd FZC**  
Facility No. 116, Fujairah Free Zone, Fujairah, United Arab Emirates

List of medical devices covered by the EC Design-Examination Certificate:

Brand Name: High Track

MODEL NUMBER	SIZE (Balloon Dia. x Length)	MODEL NUMBER	SIZE (Balloon Dia. x Length)
VM-HT-250-10	2.50 X 10 MM	VM-HT-325-18	3.25 X 18 MM
VM-HT-250-12	2.50 X 12 MM	VM-HT-325-20	3.25 X 20 MM
VM-HT-250-14	2.50 X 14 MM	VM-HT-325-23	3.25 X 23 MM
VM-HT-250-15	2.50 X 15 MM	VM-HT-325-25	3.25 X 25 MM
VM-HT-250-16	2.50 X 16 MM	VM-HT-325-30	3.25 X 30 MM
VM-HT-250-18	2.50 X 18 MM	VM-HT-350-10	3.50 X 10 MM
VM-HT-250-20	2.50 X 20 MM	VM-HT-350-12	3.50 X 12 MM
VM-HT-250-23	2.50 X 23 MM	VM-HT-350-14	3.50 X 14 MM
VM-HT-250-25	2.50 X 25 MM	VM-HT-350-15	3.50 X 15 MM
VM-HT-250-30	2.50 X 30 MM	VM-HT-350-16	3.50 X 16 MM
VM-HT-275-10	2.75 X 10 MM	VM-HT-350-18	3.50 X 18 MM
VM-HT-275-12	2.75 X 12 MM	VM-HT-350-20	3.50 X 20 MM
VM-HT-275-14	2.75 X 14 MM	VM-HT-350-23	3.50 X 23 MM
VM-HT-275-15	2.75 X 15 MM	VM-HT-350-25	3.50 X 25 MM
VM-HT-275-16	2.75 X 16 MM	VM-HT-350-30	3.50 X 30 MM
VM-HT-275-18	2.75 X 18 MM	VM-HT-375-10	3.75 X 10 MM
VM-HT-275-20	2.75 X 20 MM	VM-HT-375-12	3.75 X 12 MM
VM-HT-275-23	2.75 X 23 MM	VM-HT-375-14	3.75 X 14 MM
VM-HT-275-25	2.75 X 25 MM	VM-HT-375-15	3.75 X 15 MM
VM-HT-275-30	2.75 X 30 MM	VM-HT-375-16	3.75 X 16 MM
VM-HT-300-10	3.00 X 10 MM	VM-HT-375-18	3.75 X 18 MM
VM-HT-300-12	3.00 X 12 MM	VM-HT-375-20	3.75 X 20 MM
VM-HT-300-14	3.00 X 14 MM	VM-HT-375-23	3.75 X 23 MM
VM-HT-300-15	3.00 X 15 MM	VM-HT-375-25	3.75 X 25 MM
VM-HT-300-16	3.00 X 16 MM	VM-HT-375-30	3.75 X 30 MM
VM-HT-300-18	3.00 X 18 MM	VM-HT-400-10	4.00 X 10 MM
VM-HT-300-20	3.00 X 20 MM	VM-HT-400-12	4.00 X 12 MM
VM-HT-300-23	3.00 X 23 MM	VM-HT-400-14	4.00 X 14 MM
VM-HT-300-25	3.00 X 25 MM	VM-HT-400-15	4.00 X 15 MM
VM-HT-300-30	3.00 X 30 MM	VM-HT-400-16	4.00 X 16 MM
VM-HT-325-10	3.25 X 10 MM	VM-HT-400-18	4.00 X 18 MM
VM-HT-325-12	3.25 X 12 MM	VM-HT-400-20	4.00 X 20 MM
VM-HT-325-14	3.25 X 14 MM	VM-HT-400-23	4.00 X 23 MM
VM-HT-325-15	3.25 X 15 MM	VM-HT-400-25	4.00 X 25 MM
VM-HT-325-16	3.25 X 16 MM	VM-HT-400-30	4.00 X 30 MM

Page 1 of 1



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

At Bratislava, on May 25<sup>th</sup>, 2021  
Valid until May 26<sup>th</sup>, 2024