



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

EC DESIGN-EXAMINATION CERTIFICATE

No. 2019-MDD/DE-061

issued in compliance with the Council Directive 93/42/EEC as amended 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the design of medical device of Class III,

High pressure low complaint rapid exchange PTCA balloon catheter
Brand Name: High Track
(for detailed list refer to Annex; page 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 on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC taking into account intended use 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. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310421/2019.

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 26th, 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 by 2007/47/EC, Annex II (excluding 4).




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

In Bratislava, on October 9th, 2019



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

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)
VM-HT-250-10	2.50 X 10 MM
VM-HT-250-15	2.50 X 15 MM
VM-HT-250-20	2.50 X 20 MM
VM-HT-250-30	2.50 X 30 MM
VM-HT-275-10	2.75 X 10 MM
VM-HT-275-15	2.75 X 15 MM
VM-HT-275-20	2.75 X 20 MM
VM-HT-275-30	2.75 X 30 MM
VM-HT-300-10	3.00 X 10 MM
VM-HT-300-15	3.00 X 15 MM
VM-HT-300-20	3.00 X 20 MM
VM-HT-300-30	3.00 X 30 MM
VM-HT-325-10	3.25 X 10 MM
VM-HT-325-15	3.25 X 15 MM
VM-HT-325-20	3.25 X 20 MM
VM-HT-325-30	3.25 X 30 MM
VM-HT-350-10	3.50 X 10 MM
VM-HT-350-15	3.50 X 15 MM
VM-HT-350-20	3.50 X 20 MM
VM-HT-350-30	3.50 X 30 MM
VM-HT-375-10	3.75 X 10 MM
VM-HT-375-15	3.75 X 15 MM
VM-HT-375-20	3.75 X 20 MM
VM-HT-375-30	3.75 X 30 MM
VM-HT-400-10	4.00 X 10 MM
VM-HT-400-15	4.00 X 15 MM
VM-HT-400-20	4.00 X 20 MM
VM-HT-400-30	4.00 X 30 MM

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Valid until May 26th, 2024