



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

# EC DESIGN-EXAMINATION CERTIFICATE

No. 2019-MDD/DE-063

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,

**Percutaneous Transluminal Angioplasty (PTA) Catheters**  
**Brand Name: Indigo Rx and Indigo OTW**  
(for detailed list refer to Annex; pages 1 to 4)

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-063

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: Indigo Rx and Indigo OTW

MODEL AND SIZE DETAILS OF INDIGO RX AND INDIGO OTW PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER			
4.5 x 20, WL-40	VM-INRX-45-20-40	6.0 x 20, WL-40	VM-INRX-60-20-40
4.5 x 20, WL-60	VM-INRX-45-20-60	6.0 x 20, WL-60	VM-INRX-60-20-60
4.5 x 20, WL-80	VM-INRX-45-20-80	6.0 x 20, WL-80	VM-INRX-60-20-80
4.5 x 20, WL-130	VM-INRX-45-20-130	6.0 x 20, WL-130	VM-INRX-60-20-130
4.5 x 40, WL-40	VM-INRX-45-40-40	6.0 x 40, WL-40	VM-INRX-60-40-40
4.5 x 40, WL-60	VM-INRX-45-40-60	6.0 x 40, WL-60	VM-INRX-60-40-60
4.5 x 40, WL-80	VM-INRX-45-40-80	6.0 x 40, WL-80	VM-INRX-60-40-80
4.5 x 40, WL-130	VM-INRX-45-40-130	6.0 x 40, WL-130	VM-INRX-60-40-130
4.5 x 60, WL-40	VM-INRX-45-60-40	6.0 x 60, WL-40	VM-INRX-60-60-40
4.5 x 60, WL-60	VM-INRX-45-60-60	6.0 x 60, WL-60	VM-INRX-60-60-60
4.5 x 60, WL-80	VM-INRX-45-60-80	6.0 x 60, WL-80	VM-INRX-60-60-80
4.5 x 60, WL-130	VM-INRX-45-60-130	6.0 x 60, WL-130	VM-INRX-60-60-130
4.5 x 80, WL-40	VM-INRX-45-80-40	6.0 x 80, WL-40	VM-INRX-60-80-40
4.5 x 80, WL-60	VM-INRX-45-80-60	6.0 x 80, WL-60	VM-INRX-60-80-60
4.5 x 80, WL-80	VM-INRX-45-80-80	6.0 x 80, WL-80	VM-INRX-60-80-80
4.5 x 80, WL-130	VM-INRX-45-80-130	6.0 x 80, WL-130	VM-INRX-60-80-130
5.0 x 20, WL-40	VM-INRX-50-20-40	7.0 x 20, WL-40	VM-INRX-70-20-40
5.0 x 20, WL-60	VM-INRX-50-20-60	7.0 x 20, WL-60	VM-INRX-70-20-60
5.0 x 20, WL-80	VM-INRX-50-20-80	7.0 x 20, WL-80	VM-INRX-70-20-80
5.0 X 20, WL-130	VM-INRX-50-20-130	7.0 X 20, WL-130	VM-INRX-70-20-130
5.0 x 40, WL-40	VM-INRX-50-40-40	7.0 x 40, WL-40	VM-INRX-70-40-40

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

In Bratislava, on October 9<sup>th</sup>, 2019  
Valid until May 26<sup>th</sup>, 2024





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5.0 x 40, WL-60	VM-INRX-50-40-60		7.0 x 40, WL-60	VM-INRX-70-40-60
5.0 x 40, WL-80	VM-INRX-50-40-80		7.0 x 40, WL-80	VM-INRX-70-40-80
5.0 x 40, WL-130	VM-INRX-50-40-130		7.0 x 40, WL-130	VM-INRX-70-40-130
5.0 x 60, WL-40	VM-INRX-50-60-40		7.0 x 60, WL-40	VM-INRX-70-60-40
5.0 x 60, WL-60	VM-INRX-50-60-60		7.0 x 60, WL-60	VM-INRX-70-60-60
5.0 x 60, WL-80	VM-INRX-50-60-80		7.0 x 60, WL-80	VM-INRX-70-60-80
5.0 x 60, WL-130	VM-INRX-50-60-130		7.0 x 60, WL-130	VM-INRX-70-60-130
5.0 x 80, WL-40	VM-INRX-50-80-40		7.0 x 80, WL-40	VM-INRX-70-80-40
5.0 x 80, WL-60	VM-INRX-50-80-60		7.0 x 80, WL-60	VM-INRX-70-80-60
5.0 x 80, WL-80	VM-INRX-50-80-80		7.0 x 80, WL-80	VM-INRX-70-80-80
5.0 x 80, WL-130	VM-INRX-50-80-130		7.0 x 80, WL-130	VM-INRX-70-80-130
4.5 x 20, WL-40	VM-INOTW45-20-40		7.0 x 60, WL-40	VM-INOTW-70-60-40
4.5 x 20, WL-60	VM-INOTW-45-20-60		7.0 x 60, WL-60	VM-INOTW-70-60-60
4.5 x 20, WL-80	VM-INOTW-45-20-80		7.0 x 60, WL-80	VM-INOTW-70-60-80
4.5 x 20, WL-130	VM-INOTW-45-20-130		7.0 x 60, WL-130	VM-INOTW-70-60-130
4.5 x 40, WL-40	VM-INOTW-45-40-40		7.0 x 80, WL-40	VM-INOTW-70-80-40
4.5 x 40, WL-60	VM-INOTW-45-40-60		7.0 x 80, WL-60	VM-INOTW-70-80-60
4.5 x 40, WL-80	VM-INOTW-45-40-80		7.0 x 80, WL-80	VM-INOTW-70-80-80
4.5 x 40, WL-130	VM-INOTW-45-40-130		7.0 x 80, WL-130	VM-INOTW-70-80-130
4.5 x 60, WL-40	VM-INOTW-45-60-40		8.0 x 20, WL-40	VM-INOTW-80-20-40
4.5 x 60, WL-60	VM-INOTW-45-60-60		8.0 x 20, WL-60	VM-INOTW-80-20-60
4.5 x 60, WL-80	VM-INOTW-45-60-80		8.0 x 20, WL-80	VM-INOTW-80-20-80

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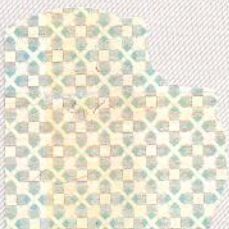
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4.5 x 80, WL-40	VM-INOTW-45-80-40	8.0 x 40, WL-40	VM-INOTW-80-40-40
4.5 x 80, WL-60	VM-INOTW-45-80-60	8.0 x 40, WL-60	VM-INOTW80-40-60
4.5 x 80, WL-80	VM-INOTW-45-80-80	8.0 x 40, WL-80	VM-INOTW-80-40-80
4.5 x 80, WL-130	VM-INOTW-45-80-130	8.0 x 40, WL-130	VM-INOTW-80-40-130
5.0 x 20, WL-40	VM-INOTW-50-20-40	8.0 x 60, WL-40	VM-INOTW-80-60-40
5.0 x 20, WL-60	VM-INOTW-50-20-60	8.0 x 60, WL-60	VM-INOTW-80-60-60
5.0 x 20, WL-80	VM-INOTW-50-20-80	8.0 x 60, WL-80	VM-INOTW-80-60-80
5.0 x 20, WL-130	VM-INOTW-50-20-130	8.0 x 60, WL-130	VM-INOTW-80-60-130
5.0 x 40, WL-40	VM-INOTW-50-40-40	8.0 x 80, WL-40	VM-INOTW-80-80-40
5.0 x 40, WL-60	VM-INOTW-50-40-60	8.0 x 80, WL-60	VM-INOTW-80-80-60
5.0 x 40, WL-80	VM-INOTW-50-40-80	8.0 x 80, WL-80	VM-INOTW-80-80-80
5.0 x 40, WL-130	VM-INOTW-50-40-130	8.0 x 80, WL-130	VM-INOTW-80-80-130
5.0 x 60, WL-40	VM-INOTW-50-60-40	9.0 x 20, WL-40	VM-INOTW-90-20-40
5.0 x 60, WL-60	VM-INOTW-50-60-60	9.0 x 20, WL-60	VM-INOTW-90-20-60
5.0 x 60, WL-80	VM-INOTW-50-60-80	9.0 x 20, WL-80	VM-INOTW-90-20-80
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5.0 x 80, WL-40	VM-INOTW50-80-40	9.0 x 40, WL-40	VM-INOTW-90-40-40
5.0 x 80, WL-60	VM-INOTW-50-80-60	9.0 x 40, WL-60	VM-INOTW-90-40-60
5.0 x 80, WL-80	VM-INOTW-50-80-80	9.0 x 40, WL-80	VM-INOTW-90-40-80
5.0 x 80, WL-130	VM-INOTW-50-80-130	9.0 x 40, WL-130	VM-INOTW-90-40-130
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6.0 x 20, WL-60	VM-INOTW-60-20-60	9.0 x 60, WL-60	VM-INOTW-90-60-60

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

In Bratislava, on October 9<sup>th</sup>, 2019  
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6.0 x 80, WL-80	VM-INOTW-60-80-80	10.0 x 40, WL-80	VM-INOTW-10-40-80
6.0 x 80, WL-130	VM-INOTW-60-80-130	10.0 x 40, WL-130	VM-INOTW10-40-130
7.0 x 20, WL-40	VM-INOTW-70-20-40	10.0 x 60, WL-40	VM-INOTW-10-60-40
7.0 x 20, WL-60	VM-INOTW-70-20-60	10.0 x 60, WL-60	VM-INOTW-10-60-60
7.0 x 20, WL-80	VM-INOTW-70-20-80	10.0 x 60, WL-80	VM-INOTW-10-60-80
7.0 x 20, WL-130	VM-INOTW-70-20-130	10.0 x 60, WL-130	VM-INOTW-10-60-130
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7.0 x 40, WL-60	VM-INOTW-70-40-60	10.0 x 80, WL-60	VM-INOTW-10-80-60
7.0 x 40, WL-80	VM-INOTW-70-40-80	10.0 x 80, WL-80	VM-INOTW-10-80-80
7.0 x 40, WL-130	VM-INOTW-70-40-130	10.0 x 80, WL-130	VM-INOTW-10-80-130

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