



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

## EC CERTIFICATE

No. 2019-MDD/QS-062

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

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

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 by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 02-127-19 and the Final protocol No. 310421/2019.

*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 by 2007/47/EC, Annex II (4) is required.



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

In Bratislava, on October 9th, 2019



## ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-062

issued for the company

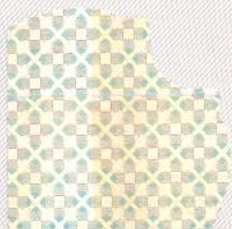
**Vasmed Technologies Ltd FZC**  
Facility No. 116, Fujairah Free Zone, Fujairah, United Arab Emirates

List of medical devices covered by the EC Certificate:

Brand Name: 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

Page 1 of 4



Dr. Katarina Tomin 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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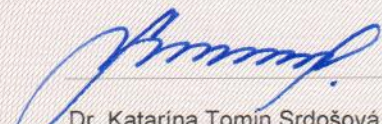
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Brand Name: Indigo Rx and Indigo OTW

MODEL AND SIZE DETAILS OF INDIGO RX AND INDIGO OTW PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER				
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

Page 2 of 4



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

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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-INOTW-80-40-60
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
5.0 x 60, WL-130	VM-INOTW-50-60-130	9.0 x 20, WL-130	VM-INOTW-90-20-130
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
6.0 x 20, WL-40	VM-INOTW-60-20-40	9.0 x 60, WL-40	VM-INOTW-90-60-40
6.0 x 20, WL-60	VM-INOTW-60-20-60	9.0 x 60, WL-60	VM-INOTW-90-60-60

Page 3 of 4



*[Signature]*  
 Dr. Katarina Tomin Srdošová  
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In Bratislava, on October 9<sup>th</sup>, 2019  
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6.0 x 40, WL-40	VM-INOTW-60-40-40	9.0 x 80, WL-40	VM-INOTW-90-80-40
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6.0 x 80, WL-60	VM-INOTW-60-80-60	10.0 x 40, WL-60	VM-INOTW10-40-60
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
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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-80	VM-INOTW-70-40-80	10.0 x 80, WL-80	VM-INOTW-10-80-80
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