



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

EC CERTIFICATE

No. 2021-MDD/QS-037

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

ACCEX PTCA GUIDEWIRE

(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

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_189 and the Final protocol No. 310518/2021.

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

At Bratislava, on May 6th, 2021



ANNEX TO EC CERTIFICATE No. 2021-MDD/QS-037

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:

Product name: ACCEX PTCA GUIDEWIRE

Variants	Tip Shape	Product Code
Accex Floppy	J tip/Straight tip	VM-AX-014-FJ-185
		VM-AX-014-FS-185
Accex Regular	J tip/Straight tip	VM-AX-014-RJ-185
		VM-AX-014-RS-185
Accex Extra Support	J tip/Straight tip	VM-AX-014-ESJ-185
		VM-AX-014-ESS-185

Page 1 of 1



At Bratislava, on May 6th, 2021
Valid until May 26th, 2024

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

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	May 6 th , 2021	310518	First issue of the Certificate

Vasmed Technologies Ltd Fzc
Plot No. L314 , Fujairah Freezone
1356 Fujairah
UAE

Attn. Jayaprasad Pillai, managing director

Our reference
MIT/2023/P022

Contact person
Michal Tomin / +421 915 366 774

BRATISLAVA
15.11.2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Vasmed Technologies Ltd Fzc
Plot No. L314 , Fujairah Freezone
1356 Fujairah
UAE

SRN Number (if available): AE-MF-000019360

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

3EC International a.s. 
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
MAT No.: SK2022390073

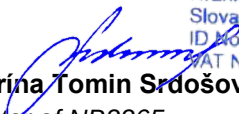

Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sirolimus Drug Eluting Cobalt Chromium Coronary Stent mounted on PTCA Balloon Catheter - Brand Name: RAPSTROM Model: VM-VTR-250-8 – VARIANTS (Balloon Dia x Length) 2.50 X 8 MM Model: VM-VTR-250-13 – VARIANTS (Balloon Dia x Length) 2.50 X 13 MM Model: VM-VTR-250-18 – VARIANTS (Balloon Dia x Length) 2.50 X 18 MM Model: VM-VTR-250-23 – VARIANTS (Balloon Dia x Length) 2.50 X 23 MM Model: VM-VTR-250-28– VARIANTS (Balloon Dia x Length) 2.50 X 28 MM	Class III	N/A	2019-MDD/QS-056; NB2265 2019-MDD/DE-057; NB2265

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia IČO: 36 789 003 IČ DPH: SK2022390073
Tel/Fax: 00421 (0)2 5831 8343 / - 45 e-mail: info@3ec.sk web: http://www.3ec.sk

♦ effectiveness ♦ efficiency ♦ excellence ♦

Model: VM-VTR-250-33 – VARIANTS (Balloon Dia x Length) 2.50 X 33 MM			
Model: VM-VTR-250-38 – VARIANTS (Balloon Dia x Length) 2.50 X 38 MM			
Model: VM-VTR-275-8 – VARIANTS (Balloon Dia x Length) 2.75 X 8 MM			
Model: VM-VTR-275-13 – VARIANTS (Balloon Dia x Length) 2.75 X 13 MM			
Model: VM-VTR-275-18 – VARIANTS (Balloon Dia x Length) 2.75 X 18 MM			
Model: VM-VTR-275-23 – VARIANTS (Balloon Dia x Length) 2.75 X 23 MM			
Model: VM-VTR-275-28 – VARIANTS (Balloon Dia x Length) 2.75 X 28 MM			
Model: VM-VTR-275-33 – VARIANTS (Balloon Dia x Length) 2.75 X 33 MM			
Model: VM-VTR-275-38 – VARIANTS (Balloon Dia x Length) 2.75 X 38 MM			
Model: VM-VTR-300-8 – VARIANTS (Balloon Dia x Length) 3.00 X 8 MM			
Model: VM-VTR-300-13 – VARIANTS (Balloon Dia x Length) 3.00 X 13 MM			
Model: VM-VTR-300-18 – VARIANTS (Balloon Dia x Length) 3.00 X 18 MM			
Model: VM-VTR-300-23 – VARIANTS (Balloon Dia x Length) 3.00 X 23 MM			
Model: VM-VTR-300-28 – VARIANTS (Balloon Dia x Length) 3.00 X 28 MM			
Model: VM-VTR-300-33 – VARIANTS (Balloon Dia x Length) 3.00 X 33 MM			
Model: VM-VTR-300-38 – VARIANTS (Balloon Dia x Length) 3.00 X 38 MM			
Model: VM-VTR-325-8 – VARIANTS (Balloon Dia x Length) 3.25 X 8 MM			
Model: VM-VTR-325-13 – VARIANTS (Balloon Dia x Length) 3.25 X 13 MM			

Model: VM-VTR-325-18 – VARIANTS (Balloon Dia x Length) 3.25 X 18 MM			
Model: VM-VTR-325-23 – VARIANTS (Balloon Dia x Length) 3.25 X 23 MM			
Model: VM-VTR-325-28 – VARIANTS (Balloon Dia x Length) 3.25 X 28 MM			
Model: VM-VTR-325-33 – VARIANTS (Balloon Dia x Length) 3.25 X 33 MM			
Model: VM-VTR-325-38 – VARIANTS (Balloon Dia x Length) 3.25 X 38 MM			
Model: VM-VTR-350-8 – VARIANTS (Balloon Dia x Length) 3.50 X 8 MM			
Model: VM-VTR-350-13 – VARIANTS (Balloon Dia x Length) 3.50 X 13 MM			
Model: VM-VTR-350-18 – VARIANTS (Balloon Dia x Length) 3.50 X 18 MM			
Model: VM-VTR-350-23 – VARIANTS (Balloon Dia x Length) 3.50 X 23 MM			
Model: VM-VTR-350-28 – VARIANTS (Balloon Dia x Length) 3.50 X 28 MM			
Model: VM-VTR-350-33 – VARIANTS (Balloon Dia x Length) 3.50 X 33 MM			
Model: VM-VTR-350-38 – VARIANTS (Balloon Dia x Length) 3.50 X 38 MM			
Model: VM-VTR-375-8 – VARIANTS (Balloon Dia x Length) 3.75 X 8 MM			
Model: VM-VTR-375-13 – VARIANTS (Balloon Dia x Length) 3.75 X 13 MM			
Model: VM-VTR-375-18 – VARIANTS (Balloon Dia x Length) 3.75 X 18 MM			
Model: VM-VTR-375-23 – VARIANTS (Balloon Dia x Length) 3.75 X 23 MM			
Model: VM-VTR-375-28 – VARIANTS (Balloon Dia x Length) 3.75 X 28 MM			
Model: VM-VTR-375-33 – VARIANTS (Balloon Dia x Length) 3.75 X 33 MM			

Model: VM-VTR-375-38 – VARIANTS (Balloon Dia x Length) 3.75 X 38 MM Model: VM-VTR-400-8 – VARIANTS (Balloon Dia x Length) 4.00 X 8 MM Model: VM-VTR-400-13 – VARIANTS (Balloon Dia x Length) 4.00 X 13 MM Model: VM-VTR-400-18 – VARIANTS (Balloon Dia x Length) 4.00 X 18 MM Model: VM-VTR-400-23 – VARIANTS (Balloon Dia x Length) 4.00 X 23 MM Model: VM-VTR-400-28 – VARIANTS (Balloon Dia x Length) 4.00 X 28 MM Model: VM-VTR-400-33 – VARIANTS (Balloon Dia x Length) 4.00 X 33 MM Model: VM-VTR-400-38 – VARIANTS (Balloon Dia x Length) 4.00 X 38 MM Brand Name: AKOS Model: VM-VTA-250-8 – VARIANTS (Balloon Dia x Length) 2.50 X 8 MM Model: VM-VTA-250-13 – VARIANTS (Balloon Dia x Length) 2.50 X 3 MM Model: VM-VTA-250-18 – VARIANTS (Balloon Dia x Length) 2.50 X 18 MM Model: VM-VTA-250-23 – VARIANTS (Balloon Dia x Length) 2.50 X 23 MM Model: VM-VTA -250-28– VARIANTS (Balloon Dia x Length) 2.50 X 28 MM Model: VM-VTA -250-33 – VARIANTS (Balloon Dia x Length) 2.50 X 33 MM Model: VM-VTA -250-38– VARIANTS (Balloon Dia x Length) 2.50 X 38 MM Model: VM-VTA -275-8 – VARIANTS (Balloon Dia x Length) 2.75 X 8 MM Model: VM-VTA -275-13 – VARIANTS (Balloon Dia x Length) 2.75 X 13 MM			
---	--	--	--

Model: VM-VTA -275-18 – VARIANTS (Balloon Dia x Length) 2.75 X 18 MM			
Model: VM-VTA -275-23 – VARIANTS (Balloon Dia x Length) 2.75 X 23 MM			
Model: VM-VTA -275-28 – VARIANTS (Balloon Dia x Length) 2.75 X 28 MM			
Model: VM-VTA -275-33– VARIANTS (Balloon Dia x Length) 2.75 X 33 MM			
Model: VM-VTA-275-38 – VARIANTS (Balloon Dia x Length) 2.75 X 38 MM			
Model: VM-VTA-300-8 – VARIANTS (Balloon Dia x Length) 3.00 X 8 MM			
Model: VM-VTA-300-13 – VARIANTS (Balloon Dia x Length) 3.00 X 13 MM			
Model: VM-VTA-300-18 – VARIANTS (Balloon Dia x Length) 3.00 X 18 MM			
Model: VM-VTA-300-23 – VARIANTS (Balloon Dia x Length) 3.00 X 23 MM			
Model: VM-VTA-300-28 – VARIANTS (Balloon Dia x Length) 3.00 X 28 MM			
Model: VM-VTA-300-33 – VARIANTS (Balloon Dia x Length) 3.00 X 33 MM			
Model: VM-VTA-300-38 – VARIANTS (Balloon Dia x Length) 3.00 X 38 MM			
Model: VM-VTA-325-8 – VARIANTS (Balloon Dia x Length) 3.25 X 8 MM			
Model: VM-VTA-325-13 – VARIANTS (Balloon Dia x Length) 3.25 X 13 MM			
Model: VM-VTA-325-18 – VARIANTS (Balloon Dia x Length) 3.25 X 18 MM			
Model: VM-VTA-325-23 – VARIANTS (Balloon Dia x Length) 3.25 X 23 MM			
Model: VM-VTA-325-28 – VARIANTS (Balloon Dia x Length) 3.25 X 28 MM			
Model: VM-VTA-325-33 – VARIANTS (Balloon Dia x Length) 3.25 X 33 MM			

Model: VM-VTA-325-38 – VARIANTS (Balloon Dia x Length) 3.25 X 38 MM			
Model: VM-VTA-350-8 – VARIANTS (Balloon Dia x Length) 3.50 X 8 MM			
Model: VM-VTA-350-13 – VARIANTS (Balloon Dia x Length) 3.50 X 13 MM			
Model: VM-VTA-350-18 – VARIANTS (Balloon Dia x Length) 3.50 X 18 MM			
Model: VM-VTA-350-23 – VARIANTS (Balloon Dia x Length) 3.50 X 23 MM			
Model: VM-VTA-350-28 – VARIANTS (Balloon Dia x Length) 3.50 X 28 MM			
Model: VM-VTA-350-33 – VARIANTS (Balloon Dia x Length) 3.50 X 33 MM			
Model: VM-VTA-350-38 – VARIANTS (Balloon Dia x Length) 3.50 X 38 MM			
Model: VM-VTA-375-8 – VARIANTS (Balloon Dia x Length) 3.75 X 8 MM			
Model: VM-VTA-375-13 – VARIANTS (Balloon Dia x Length) 3.75 X 13 MM			
Model: VM-VTA-375-18 – VARIANTS (Balloon Dia x Length) 3.75 X 18 MM			
Model: VM-VTA-375-23 – VARIANTS (Balloon Dia x Length) 3.75 X 23 MM			
Model: VM-VTA-375-28 – VARIANTS (Balloon Dia x Length) 3.75 X 28 MM			
Model: VM-VTA-375-33 – VARIANTS (Balloon Dia x Length) 3.75 X 33 MM			
Model: VM-VTA-375-38 – VARIANTS (Balloon Dia x Length) 3.75 X 38 MM			
Model: VM-VTA-400-8 – VARIANTS (Balloon Dia x Length) 4.00 X 8 MM			
Model: VM-VTA-400-13 – VARIANTS (Balloon Dia x Length) 4.00 X 13 MM			
Model: VM-VTA-400-18 – VARIANTS (Balloon Dia x Length) 4.00 X 18 MM			

Model: VM-VTA-400-23 – VARIANTS (Balloon Dia x Length) 4.00 X 23 MM Model: VM-VTA-400-28 – VARIANTS (Balloon Dia x Length) 4.00 X 28 MM Model: VM-VTA-400-33 – VARIANTS (Balloon Dia x Length) 4.00 X 33 MM Model: VM-VTA-400-38 – VARIANTS (Balloon Dia x Length) 4.00 X 38 MM Brand Name: RAPSTROM Elite Model: VM-VTE-250-8 – VARIANTS (Balloon Dia x Length) 2.50 X 8 MM Model: VM-VTE-250-13 – VARIANTS (Balloon Dia x Length) 2.50 X 13 MM Model: VM-VTE-250-18 – VARIANTS (Balloon Dia x Length) 2.50 X 18 MM Model: VM-VTE-250-23 – VARIANTS (Balloon Dia x Length) 2.50 X 23 MM Model: VM-VTE-250-28 – VARIANTS (Balloon Dia x Length) 2.50 X 28 MM Model: VM-VTE-250-33 – VARIANTS (Balloon Dia x Length) 2.50 X 33 MM Model: VM-VTE-250-38 – VARIANTS (Balloon Dia x Length) 2.50 X 38 MM Model: VM-VTE-275-8 – VARIANTS (Balloon Dia x Length) 2.75 X 8 MM Model: VM-VTE-275-13 – VARIANTS (Balloon Dia x Length) 2.75 X 13 MM Model: VM-VTE-275-18 – VARIANTS (Balloon Dia x Length) 2.75 X 18 MM Model: VM-VTE-275-23 – VARIANTS (Balloon Dia x Length) 2.75 X 23 MM Model: VM-VTE-275-28 – VARIANTS (Balloon Dia x Length) 2.75 X 28 MM Model: VM-VTE-275-33 – VARIANTS (Balloon Dia x Length) 2.75 X 33 MM			
---	--	--	--

Model: VM-VTE-275-38 – VARIANTS (Balloon Dia x Length) 2.75 X 38 MM			
Model: VM-VTE-300-8 – VARIANTS (Balloon Dia x Length) 3.00 X 8 MM			
Model: VM-VTE-300-13 – VARIANTS (Balloon Dia x Length) 3.00 X 13 MM			
Model: VM-VTE-300-18 – VARIANTS (Balloon Dia x Length) 3.00 X 18 MM			
Model: VM-VTE-300-23 – VARIANTS (Balloon Dia x Length) 3.00 X 23 MM			
Model: VM-VTE-300-28 – VARIANTS (Balloon Dia x Length) 3.00 X 28 MM			
Model: VM-VTE-300-33 – VARIANTS (Balloon Dia x Length) 3.00 X 33 MM			
Model: VM-VTE-300-38 – VARIANTS (Balloon Dia x Length) 3.00 X 38 MM			
Model: VM-VTE-325-8 – VARIANTS (Balloon Dia x Length) 3.25 X 8 MM			
Model: VM-VTE-325-13 – VARIANTS (Balloon Dia x Length) 3.25 X 13 MM			
Model: VM-VTE-325-18 – VARIANTS (Balloon Dia x Length) 3.25 X 18 MM			
Model: VM-VTE-325-23 – VARIANTS (Balloon Dia x Length) 3.25 X 23 MM			
Model: VM-VTE-325-28 – VARIANTS (Balloon Dia x Length) 3.25 X 28 MM			
Model: VM-VTE-325-33 – VARIANTS (Balloon Dia x Length) 3.25 X 33 MM			
Model: VM-VTE-325-38 – VARIANTS (Balloon Dia x Length) 3.25 X 38 MM			
Model: VM-VTE-350-8 – VARIANTS (Balloon Dia x Length) 3.50 X 8 MM			
Model: VM-VTE-350-13 – VARIANTS (Balloon Dia x Length) 3.50 X 13 MM			
Model: VM-VTE-350-18 – VARIANTS (Balloon Dia x Length) 3.50 X 18 MM			

Model: VM-VTE-350-23 – VARIANTS (Balloon Dia x Length) 3.50 X 23 MM			
Model: VM-VTE-350-28 – VARIANTS (Balloon Dia x Length) 3.50 X 28 MM			
Model: VM-VTE-350-33 – VARIANTS (Balloon Dia x Length) 3.50 X 33 MM			
Model: VM-VTE-350-38 – VARIANTS (Balloon Dia x Length) 3.50 X 38 MM			
Model: VM-VTE-375-8 – VARIANTS (Balloon Dia x Length) 3.75 X 8 MM			
Model: VM-VTE-375-13 – VARIANTS (Balloon Dia x Length) 3.75 X 13 MM			
Model: VM-VTE-375-18 – VARIANTS (Balloon Dia x Length) 3.75 X 18 MM			
Model: VM-VTE-375-23 – VARIANTS (Balloon Dia x Length) 3.75 X 23 MM			
Model: VM-VTE-375-28 – VARIANTS (Balloon Dia x Length) 3.75 X 28 MM			
Model: VM-VTE-375-33 – VARIANTS (Balloon Dia x Length) 3.75 X 33 MM			
Model: VM-VTE-375-38 – VARIANTS (Balloon Dia x Length) 3.75 X 38 MM			
Model: VM-VTE-400-8 – VARIANTS (Balloon Dia x Length) 4.00 X 8 MM			
Model: VM-VTE-400-13 – VARIANTS (Balloon Dia x Length) 4.00 X 13 MM			
Model: VM-VTE-400-18 – VARIANTS (Balloon Dia x Length) 4.00 X 18 MM			
Model: VM-VTE-400-23 – VARIANTS (Balloon Dia x Length) 4.00 X 23 MM			
Model: VM-VTE-400-28 – VARIANTS (Balloon Dia x Length) 4.00 X 28 MM			
Model: VM-VTE-400-33 – VARIANTS (Balloon Dia x Length) 4.00 X 33 MM			
Model: VM-VTE-400-38 – VARIANTS (Balloon Dia x Length) 4.00 X 38 MM			

PTA Balloon Catheter – Brand Name : Indigo RX Model: VM-INRX-45-20-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-40 Model: VM-INRX-45-20-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-60 Model: VM-INRX-45-20-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-80 Model: VM-INRX-45-20-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-130 Model: VM-INRX-45-40-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-40 Model: VM-INRX-45-40-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-60 Model: VM-INRX-45-40-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-80 Model: VM-INRX-45-40-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-130 Model: VM-INRX-45-60-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-40 Model: VM-INRX-45-60-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-60 Model: VM-INRX-45-60-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-80 Model: VM-INRX-45-60-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-130 Model: VM-INRX-45-80-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-40 Model: VM-INRX-45-80-60, VARIANTS (Balloon	Class III	N/A	2019-MDD/QS-062; NB2265 2019-MDD/DE-063; NB2265
--	-----------	-----	---

Dia x Length, Working Length) 4.5 x 80, WL-60 Model: VM-INRX-45-80-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-80 Model: VM-INRX-45-80-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-130 Model: VM-INRX-50-20-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-40 Model: VM-INRX-50-20-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-60 Model: VM-INRX-50-20-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-80 Model: VM-INRX-50-20-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-130 Model: VM-INRX-50-40-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-40 Model: VM-INRX-50-40-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-60 Model: VM-INRX-50-40-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-80 Model: VM-INRX-50-40-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-130 Model: VM-INRX-50-60-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-40 Model: VM-INRX-50-60-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-60 Model: VM-INRX-50-60-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-80 Model: VM-INRX-50-60-130, VARIANTS (Balloon			
---	--	--	--

Dia x Length, Working Length) 5.0 x 60, WL-130 Model: VM-INRX-50-80-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-40 Model: VM-INRX-50-80-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-60 Model: VM-INRX-50-80-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-80 Model: VM-INRX-50-80-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-130 Model: VM-INRX-60-20-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-40 Model: VM-INRX-60-20-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-60 Model: VM-INRX-60-20-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-80 Model: VM-INRX-60-20-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-130 Model: VM-INRX-60-40-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-40 Model: VM-INRX-60-40-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-60 Model: VM-INRX-60-40-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-80 Model: VM-INRX-60-40-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-130 Model: VM-INRX-60-60-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-40 Model: VM-INRX-60-60-60, VARIANTS (Balloon			
---	--	--	--

Dia x Length, Working Length) 6.0 x 60, WL-60 Model: VM-INRX-60-60-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-80 Model: VM-INRX-60-60-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-130 Model: VM-INRX-60-80-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-40 Model: VM-INRX-60-80-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-60 Model: VM-INRX-60-80-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-80 Model: VM-INRX-60-80-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-130 Model: VM-INRX-70-20-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-40 Model: VM-INRX-70-20-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-60 Model: VM-INRX-70-20-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-80 Model: VM-INRX-70-20-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-130 Model: VM-INRX-70-40-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-40 Model: VM-INRX-70-40-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-60 Model: VM-INRX-70-40-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-80 Model: VM-INRX-70-40-130, VARIANTS (Balloon			
---	--	--	--

Dia x Length, Working Length) 7.0 x 40, WL-130 Model: VM-INRX- VM-INRX-70-60-40,VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-40 Model: VM-INRX-70-60-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-60 Model: VM-INRX-70-60-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-80 Model: VM-INRX-70-60-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-130 Model: VM-INRX-70-20-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-60 Model: VM-INRX-70-80-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-40 Model: VM-INRX-70-20-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-130 Model: VM-INRX-70-80-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-60 Model: VM-INRX-70-80-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-80 Model: VM-INRX-70-80-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-130 PTA Balloon Catheter – Brand Name : Indigo OTW Model: Model: VM-INOTW-45-20-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-40 Model: VM-INOTW-45-20-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-60 Model: VM-INOTW-45-20-80, VARIANTS (Balloon			
---	--	--	--

Dia x Length, Working Length) 4.5 x 20, WL-80 Model: VM-INOTW-45-20-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 20, WL-130 Model: VM-INOTW-45-40-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-40 Model: VM-INOTW-45-40-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-60 Model: VM-INOTW-45-40-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-80 Model: VM-INOTW-45-40-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 40, WL-130 Model: VM-INOTW-45-60-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-40 Model: VM-INOTW-45-60-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-60 Model: VM-INOTW-45-60-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-80 Model: VM-INOTW-45-60-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 60, WL-130 Model: VM-INOTW-45-80-40, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-40 Model: VM-INOTW-45-80-60, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-60 Model: VM-INOTW-45-80-80, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-80 Model: VM-INOTW-45-80-130, VARIANTS (Balloon Dia x Length, Working Length) 4.5 x 80, WL-130 Model: VM-INOTW-50-20-40, VARIANTS (Balloon			
--	--	--	--

Dia x Length, Working Length) 5.0 x 20, WL-40 Model: VM-INOTW-50-20-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-60 Model: VM-INOTW-50-20-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-80 Model: V VM-INOTW-50-20-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 20, WL-130 Model: VM-INOTW-50-40-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-40 Model: VM-INOTW-50-40-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-60 Model: VM-INOTW-50-40-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-80 Model: VM-INOTW-50-40-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 40, WL-130 Model: VM-INOTW-50-60-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-40 Model: VM-INOTW-50-60-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-60 Model: VM-INOTW-50-60-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-80 Model: VM-INOTW-50-60-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 60, WL-130 Model: VM-INOTW-50-80-40, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-40 Model: VM-INOTW-50-80-60, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-60			
---	--	--	--

Model: VM-INOTW-50-80-80, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-80			
Model: VM-INOTW-50-80-130, VARIANTS (Balloon Dia x Length, Working Length) 5.0 x 80, WL-130			
Model: VM-INOTW-60-20-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-40			
Model: VM-INOTW-60-20-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-60			
Model: VM-INOTW-60-20-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-80			
Model: VM-INOTW-60-20-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 20, WL-130			
Model: VM-INOTW-60-40-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-40			
Model: VM-INOTW-60-40-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-60			
Model: VM-INOTW-60-40-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-80			
Model: VM-INOTW-60-40-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 40, WL-130			
Model: VM-INOTW-60-60-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-40			
Model: VM-INOTW-60-60-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-60			
Model: VM-INOTW-60-60-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-80			
Model: VM-INOTW-60-60-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 60, WL-130			

Model: VM-INOTW-60-80-40, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-40			
Model: VM-INOTW-60-80-60, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-60			
Model: VM-INOTW-60-80-80, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-80			
Model: VM-INOTW-60-80-130, VARIANTS (Balloon Dia x Length, Working Length) 6.0 x 80, WL-130			
Model: VM-INOTW-70-20-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-40			
Model: VM-INOTW-70-20-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-60			
Model: VM-INOTW-70-20-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-80			
Model: VM-INOTW-70-20-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 20, WL-130			
Model: VM-INOTW-70-40-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-40			
Model: VM-INOTW-70-40-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-60			
Model: VM-INOTW-70-40-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-80			
Model: VM-INOTW-70-40-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 40, WL-130			
Model: VM-INOTW-70-60-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-40			
Model: VM-INOTW-70-60-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-60			

Model: VM-INOTW-70-60-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-80			
Model: VM-INOTW-70-60-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 60, WL-130			
Model: VM-INOTW-70-80-40, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-40			
Model: VM-INOTW-70-80-60, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-60			
Model: VM-INOTW-70-80-80, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-80			
Model: VM-INOTW-70-80-130, VARIANTS (Balloon Dia x Length, Working Length) 7.0 x 80, WL-130			
Model: VM-INOTW-80-20-40, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 20, WL-40			
Model: VM-INOTW-80-20-60, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 20, WL-60			
Model: VM-INOTW-80-20-80, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 20, WL-80			
Model: VM-INOTW-80-20-130, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 20, WL-130			
Model: VM-INOTW-80-40-40, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 40, WL-40			
Model: VM-INOTW-80-40-60, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 40, WL-60			
Model: VM-INOTW-80-40-80, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 40, WL-80			
Model: VM-INOTW-80-40-130, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 40, WL-130			

Model: VM-INOTW-80-60-40, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 60, WL-40			
Model: VM-INOTW-80-60-60, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 60, WL-60			
Model: VM-INOTW-80-60-80, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 60, WL-80			
Model: VM-INOTW-80-60-130, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 60, WL-130			
Model: VM-INOTW-80-80-40, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 80, WL-40			
Model: VM-INOTW-80-80-60, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 80, WL-60			
Model: VM-INOTW-80-80-80, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 80, WL-80			
Model: VM-INOTW-80-80-130, VARIANTS (Balloon Dia x Length, Working Length) 8.0 x 80, WL-130			
Model: VM-INOTW-90-20-40, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 20, WL-40			
Model: VM-INOTW-90-20-60, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 20, WL-60			
Model: VM-INOTW-90-20-80, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 20, WL-80			
Model: VM-INOTW-90-20-130, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 20, WL-130			
Model: VM-INOTW-90-40-40, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 40, WL-40			
Model: VM-INOTW-90-40-60, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 40, WL-60			

Model: VM-INOTW-90-40-80, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 40, WL-80			
Model: VM-INOTW-90-40-130, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 40, WL-130			
Model: VM-INOTW-90-60-40, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 60, WL-40			
Model: VM-INOTW-90-60-60, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 60, WL-60			
Model: VM-INOTW-90-60-80, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 60, WL-80			
Model: VM-INOTW-90-60-130, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 60, WL-130			
Model: VM-INOTW-90-80-40, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 80, WL-40			
Model: VM-INOTW-90-80-60, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 80, WL-60			
Model: VM-INOTW-90-80-80, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 80, WL-80			
Model: VM-INOTW-90-80-130, VARIANTS (Balloon Dia x Length, Working Length) 9.0 x 80, WL-130			
Model: V VM-INOTW-10-20-40, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 20, WL-40			
Model: VM-INOTW-10-20-60, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 20, WL-60			
Model: VM-INOTW-10-20-80, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 20, WL-80			
Model: VM-INOTW-10-20-130, VARIANTS (Balloon			

Dia x Length, Working Length) 10.0 x 20, WL-130 Model: VM-INOTW-10-40-40, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 40, WL-40 Model: VM-INOTW10-40-60, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 40, WL-60 Model: VM-INOTW-10-40-80, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 40, WL-80 Model: VM-INOTW10-40-130, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 40, WL-130 Model: VM-INOTW-10-60-40, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 60, WL-40 Model: VM-INOTW-10-60-60, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 60, WL-60 Model: VM-INOTW-10-60-80, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 60, WL-80 Model: VM-INOTW-10-60-130, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 60, WL-130 Model: VM-INOTW-10-80-40, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 80, WL-40 Model: VM-INOTW-10-80-60, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 80, WL-60 Model: VM-INOTW-10-80-80, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 80, WL-80 Model: VM-INOTW-10-80-130, VARIANTS (Balloon Dia x Length, Working Length) 10.0 x 80, WL-130			
Rapid Exchange PTCA Balloon Catheter – Brand Name : Vas Track – Model: VM-VT-100-10 (Balloon Dia x Length) 1.00 x 10 mm	Class III	N/A	2019-MDD/QS-064/A; NB2265 2019-MDD/DE-065/A; NB2265

Model: VM-VT-100-15, Variants (Balloon Dia x Length) 1.00 x 15 mm			
Model: VM-VT-100-20, Variants (Balloon Dia x Length) 1.00 x 20 mm			
Model: VM-VT-100-25, Variants (Balloon Dia x Length) 1.00 x 25mm			
Model: VM-VT-100-30, Variants (Balloon Dia x Length) 1.00 x 30 mm			
Model: VM-VT-100-32, Variants (Balloon Dia x Length) 1.00 x 32 mm			
Model: VM-VT-100-34, Variants (Balloon Dia x Length) 1.00 x 34mm			
Model: VM-VT-100-36, Variants (Balloon Dia x Length) 1.00 x 36mm			
Model: VM-VT-100-38, Variants (Balloon Dia x Length) 1.00 x 38 mm			
Model: VM-VT-100-42, Variants (Balloon Dia x Length) 1.00 x 42 mm			
Model: VM-VTII-100-10 (Balloon Dia x Length) 1.00 x 10 mm			
Model: VM-VTII-100-15, Variants (Balloon Dia x Length) 1.00 x 15 mm			
Model: VM-VTII-100-20, Variants (Balloon Dia x Length) 1.00 x 20 mm			
Model: VM-VTII-100-25, Variants (Balloon Dia x Length) 1.00 x 25mm			
Model: VM-VTII-100-30, Variants (Balloon Dia x Length) 1.00 x 30 mm			
Model: VM-VTII-100-32, Variants (Balloon Dia x Length) 1.00 x 32 mm			
Model: VM-VTII-100-34, Variants (Balloon Dia x Length) 1.00 x 34mm			
Model: VM-VTII-100-36, Variants (Balloon Dia x Length) 1.00 x 36mm			
Model: VM-VTII-100-38, Variants (Balloon Dia x Length) 1.00 x 38 mm			

Model: VM-VTII-100-42, Variants (Balloon Dia x Length) 1.00 x 42 mm			
Model: VM-VT-125-10 (Balloon Dia x Length) 1.25 x 10 mm			
Model: VM-VT-125-15, Variants (Balloon Dia x Length) 1.25 x 15 mm			
Model: VM-VT-125-20, Variants (Balloon Dia x Length) 1.25 x 20 mm			
Model: VM-VT-125-25, Variants (Balloon Dia x Length) 1.25 x 25mm			
Model: VM-VT-125-30, Variants (Balloon Dia x Length) 1.25 x 30 mm			
Model: VM-VT-125-32, Variants (Balloon Dia x Length) 1.25 x 32 mm			
Model: VM-VT-125-34, Variants (Balloon Dia x Length) 1.25 x 34mm			
Model: VM-VT-125-36, Variants (Balloon Dia x Length) 1.25 x 36mm			
Model: VM-VT-125-38, Variants (Balloon Dia x Length) 1.25 x 38 mm			
Model: VM-VT-125-42, Variants (Balloon Dia x Length) 1.25 x 42 mm			
Model: VM-VTII-125-10 (Balloon Dia x Length) 1.25 x 10 mm			
Model: VM-VTII-125-15, Variants (Balloon Dia x Length) 1.25 x 15 mm			
Model: VM-VTII-125-20, Variants (Balloon Dia x Length) 1.25 x 20 mm			
Model: VM-VTII-125-25, Variants (Balloon Dia x Length) 1.25 x 25mm			
Model: VM-VTII-125-30, Variants (Balloon Dia x Length) 1.25 x 30 mm			
Model: VM-VTII-125-32, Variants (Balloon Dia x Length) 1.25 x 32 mm			
Model: VM-VTII-125-34, Variants (Balloon Dia x Length) 1.25 x 34mm			

Model: VM-VTII-125-36, Variants (Balloon Dia x Length) 1.25 x 36mm			
Model: VM-VTII-125-38, Variants (Balloon Dia x Length) 1.25 x 38 mm			
Model: VM-VTII-125-42, Variants (Balloon Dia x Length) 1.25 x 42 mm			
Model: VM-VT-150-10 (Balloon Dia x Length) 1.50 x 10 mm			
Model: VM-VT-150-15, Variants (Balloon Dia x Length) 1.50 x 15 mm			
Model: VM-VT-150-20, Variants (Balloon Dia x Length) 1.50 x 20 mm			
Model: VM-VT-150-25, Variants (Balloon Dia x Length) 1.50 x 25mm			
Model: VM-VT-150-30, Variants (Balloon Dia x Length) 1.50 x 30 mm			
Model: VM-VT-150-32, Variants (Balloon Dia x Length) 1.50 x 32 mm			
Model: VM-VT-150-34, Variants (Balloon Dia x Length) 1.50 x 34mm			
Model: VM-VT-150-36, Variants (Balloon Dia x Length) 1.50 x 36mm			
Model: VM-VT-150-38, Variants (Balloon Dia x Length) 1.50 x 38 mm			
Model: VM-VT-150-42, Variants (Balloon Dia x Length) 1.50 x 42 mm			
Model: VM-VTII-150-10 (Balloon Dia x Length) 1.50 x 10 mm			
Model: VM-VTII-150-15, Variants (Balloon Dia x Length) 1.50 x 15 mm			
Model: VM-VTII-150-20, Variants (Balloon Dia x Length) 1.50 x 20 mm			
Model: VM-VTII-150-25, Variants (Balloon Dia x Length) 1.50 x 25mm			
Model: VM-VTII-150-30, Variants (Balloon Dia x Length) 1.50 x 30 mm			

Model: VM-VTII-150-32, Variants (Balloon Dia x Length) 1.50 x 32 mm			
Model: VM-VTII-150-34, Variants (Balloon Dia x Length) 1.50 x 34mm			
Model: VM-VTII-150-36, Variants (Balloon Dia x Length) 1.50 x 36mm			
Model: VM-VTII-150-38, Variants (Balloon Dia x Length) 1.50 x 38 mm			
Model: VM-VTII-150-42, Variants (Balloon Dia x Length) 1.50 x 42 mm			
Model: VM-VT-200-10 (Balloon Dia x Length) 2.00 x 10 mm			
Model: VM-VT-200-15, Variants (Balloon Dia x Length) 2.00 x 15 mm			
Model: VM-VT-200-20, Variants (Balloon Dia x Length) 2.00 x 20 mm			
Model: VM-VT-200-25, Variants (Balloon Dia x Length) 2.00 x 25mm			
Model: VM-VT-200-30, Variants (Balloon Dia x Length) 2.00 x 30 mm			
Model: VM-VT-200-32, Variants (Balloon Dia x Length) 2.00 x 32 mm			
Model: VM-VT-200-34, Variants (Balloon Dia x Length) 2.00 x 34mm			
Model: VM-VT-200-36, Variants (Balloon Dia x Length) 2.00 x 36mm			
Model: VM-VT-200-38, Variants (Balloon Dia x Length) 2.00 x 38 mm			
Model: VM-VT-200-42, Variants (Balloon Dia x Length) 2.00 x 42 mm			
Model: VM-VTII-200-10 (Balloon Dia x Length) 2.00 x 10 mm			
Model: VM-VTII-200-15, Variants (Balloon Dia x Length) 2.00 x 15 mm			
Model: VM-VTII-200-20, Variants (Balloon Dia x Length) 2.00 x 20 mm			

Model: VM-VTII-200-25, Variants (Balloon Dia x Length) 2.00 x 25mm			
Model: VM-VTII-200-30, Variants (Balloon Dia x Length) 2.00 x 30 mm			
Model: VM-VTII-200-32, Variants (Balloon Dia x Length) 2.00 x 32 mm			
Model: VM-VTII-200-34, Variants (Balloon Dia x Length) 2.00 x 34mm			
Model: VM-VTII-200-36, Variants (Balloon Dia x Length) 2.00 x 36mm			
Model: VM-VTII-200-38, Variants (Balloon Dia x Length) 2.00 x 38 mm			
Model: VM-VTII-200-42, Variants (Balloon Dia x Length) 2.00 x 42 mm			
Model: VM-VT-250-10, Variants (Balloon Dia x Length) 2.50 X 10 MM			
Model: VM-VT-250-15 (Balloon Dia x Length) 2.50 X 15 MM			
Model: VM-VT-250-30, Variants (Balloon Dia x Length) 2.50 X 30 MM			
Model: VM-VT-250-32, Variants (Balloon Dia x Length) 2.50 X 32 MM			
Model: VM-VT-250-34, Variants (Balloon Dia x Length) 2.50 X 34 MM			
Model: VM-VT-250-36, Variants (Balloon Dia x Length) 2.50 X 36 MM			
Model: VM-VT-250-38, Variants (Balloon Dia x Length) 2.50 X 38 MM			
Model: VM-VT-250-42, Variants (Balloon Dia x Length) 2.50 X 42 MM			
Model: VM-VT-275-10, Variants (Balloon Dia x Length) 2.75 X 15 MM			
Model: VM-VT-275-20, Variants (Balloon Dia x Length) 2.75 X 20 MM			
Model: VM-VT-275-25, Variants (Balloon Dia x Length) 2.75 X 25 MM			

Model: VM-VT-275-30, Variants (Balloon Dia x Length) 2.75 X 30 MM			
Model: VM-VT-275-32, Variants (Balloon Dia x Length) 2.75 X 32 MM			
Model: VM-VT-275-34, Variants (Balloon Dia x Length) 2.75 X 34 MM			
Model: VM-VT-275-36, Variants (Balloon Dia x Length) 2.75 X 36 MM			
Model: VM-VT-275-38, Variants (Balloon Dia x Length) 2.75 X 38 MM			
Model: VM- VT-275-42, Variants (Balloon Dia x Length) 2.75 X 42 MM			
Model: VM-VT-300-10, Variants (Balloon Dia x Length) 3.00 X 10 MM			
Model: VM-VT-300-15, Variants (Balloon Dia x Length) 3.00 X 15 MM			
Model: VM-VT-300-20, Variants (Balloon Dia x Length) 3.00 X 20 MM			
Model: VM-VT-300-25, Variants (Balloon Dia x Length) 3.00 X 25 MM			
Model: VM-VT-300-30, Variants (Balloon Dia x Length) 3.00 X 30 MM			
Model: VM-VT-300-32, Variants (Balloon Dia x Length) 3.00 X 32 MM			
Model: VM-VT-300-34, Variants (Balloon Dia x Length) 3.00 X 34 MM			
Model: VM-VT-300-36, Variants (Balloon Dia x Length) 3.00 X 36 MM			
Model: VM-VT-300-38, Variants (Balloon Dia x Length) 3.00 X 38 MM			
Model: VM- VT-300-42, Variants (Balloon Dia x Length) 3.00 X 42 MM			
Model: VM-VT-325-10, Variants (Balloon Dia x Length) 3.25 X 10 MM			
Model: VM-VT-325-15, Variants (Balloon Dia x Length) 3.25 X 15 MM			

Model: VM-VT-325-20, Variants (Balloon Dia x Length) 3.25 X 20 MM			
Model: VM-VT-325-25, Variants (Balloon Dia x Length) 3.25 X 25 MM			
Model: VM-VT-325-30, Variants (Balloon Dia x Length) 3.25 X 30 MM			
Model: VM-VT-325-32, Variants (Balloon Dia x Length) 3.25 X 32 MM			
Model: VM-VT-325-34, Variants (Balloon Dia x Length) 3.25 X 34 MM			
Model: VM-VT-325-36, Variants (Balloon Dia x Length) 3.25 X 36 MM			
Model: VM-VT-325-38, Variants (Balloon Dia x Length) 3.25 X 38 MM			
Model: VM- VT-325-42, Variants (Balloon Dia x Length) 3.25 X 42 MM			
Model: VM-VT-350-10, Variants (Balloon Dia x Length) 3.50 X 10 MM			
Model: VM-VT-350-15, Variants (Balloon Dia x Length) 3.50 X 15 MM			
Model: VM-VT-350-20, Variants (Balloon Dia x Length) 3.50 X 20 MM			
Model: VM-VT-350-25, Variants (Balloon Dia x Length) 3.50 X 25 MM			
Model: VM-VT-350-30, Variants (Balloon Dia x Length) 3.50 X 30 MM			
Model: VM-VT-350-32, Variants (Balloon Dia x Length) 3.50 X 32 MM			
Model: VM-VT-350-34, Variants (Balloon Dia x Length) 3.50 X 34 MM			
Model: VM-VT-350-36, Variants (Balloon Dia x Length) 3.50 X 36 MM			
Model: VM-VT-350-38, Variants (Balloon Dia x Length) 3.50 X 38 MM			
Model: VM- VT-350-42, Variants (Balloon Dia x Length) 3.50 X 42 MM			

Model: VM-VT-375-10, Variants (Balloon Dia x Length) 3.75 X 10 MM			
Model: VM-VT-375-15, Variants (Balloon Dia x Length) 3.75 X 15 MM			
Model: VM-VT-375-20, Variants (Balloon Dia x Length) 3.75 X 20 MM			
Model: VM-VT-375-25, Variants (Balloon Dia x Length) 3.75 X 25 MM			
Model: VM-VT-375-30, Variants (Balloon Dia x Length) 3.75 X 30 MM			
Model: VM-VT-375-32, Variants (Balloon Dia x Length) 3.75 X 32 MM			
Model: VM-VT-375-34, Variants (Balloon Dia x Length) 3.75 X 34 MM			
Model: VM-VT-375-36, Variants (Balloon Dia x Length) 3.75 X 36 MM			
Model: VM-VT-375-38, Variants (Balloon Dia x Length) 3.75 X 38 MM			
Model: VM- VT-375-42, Variants (Balloon Dia x Length) 3.75 X 42 MM			
Model: VM-VT-400-10, Variants (Balloon Dia x Length) 4.00 X 10 MM			
Model: VM-VT-400-15, Variants (Balloon Dia x Length) 4.00 X 15 MM			
Model: VM-VT-400-20, Variants (Balloon Dia x Length) 4.00 X 20 MM			
Model: VM-VT-400-25, Variants (Balloon Dia x Length) 4.00 X 25 MM			
Model: VM-VT-400-30, Variants (Balloon Dia x Length) 4.00 X 30 MM			
Model: VM-VT-400-32, Variants (Balloon Dia x Length) 4.00 X 32 MM			
Model: VM-VT-400-34, Variants (Balloon Dia x Length) 4.00 X 34 MM			
Model: VM-VT-400-36, Variants (Balloon Dia x Length) 4.00 X 36 MM			

Model: VM-VT-400-38, Variants (Balloon Dia x Length) 4.00 X 38 MM Model: VM- VT-400-42, Variants (Balloon Dia x Length) 4.00 X 42 MM			
PTCA Guide Wire – Brand Name : Accex – Model: Floppy – Variants: VM-AX-014-FJ-185 Model: Floppy – Variants: VM-AX-014-FS-185 Model: Regular – Variants: VM-AX-014-RJ-185 Model: Regular – Variants: VM-AX-014-RS-185 Model: Extra Support – Variants: VM-AX-014-ESJ-185 Model: Extra Support – Variants: VM-AX-014-ESS-185	Class III	N/A	2021-MDD/QS-037; NB2265 2021-MDD/DE-038; NB2265
High Pressure Non Compliant Rapid exchange PTCA balloon catheter – Brand name: High Track – Model: VM-HT-250-10 Variants (Balloon Dia x Length): 2.50 x 10 mm Model: VM-HT-250-12 Variants (Balloon Dia x Length): 2.50 x 12 mm Model: VM-HT-250-14 Variants (Balloon Dia x Length): 2.50 x 14 mm Model: VM-HT-250-15 Variants (Balloon Dia x Length): 2.50 x 15 mm Model: VM-HT-250-16 Variants (Balloon Dia x Length): 2.50 x 16 mm Model: VM-HT-250-18 Variants (Balloon Dia x Length): 2.50 x 18 mm Model: VM-HT-250-20 Variants (Balloon Dia x Length): 2.50 x 20 mm Model: VM-HT-250-23 Variants (Balloon Dia x Length): 2.50 x 23 mm	Class III	N/A	2019-MDD/QS-060/A; NB2265 2019-MDD/QS-061/A; NB2265

Model: VM-HT-250-25 Variants (Balloon Dia x Length): 2.50 x 25 mm			
Model: VM-HT-250-30 Variants (Balloon Dia x Length): 2.50 x 30mm			
Model: VM-HT-275-10 Variants (Balloon Dia x Length): 2.75 x 10 mm			
Model: VM-HT-275-12 Variants (Balloon Dia x Length): 2.75 x 12 mm			
Model: VM-HT-275-14 Variants (Balloon Dia x Length): 2.75 x 14 mm			
Model: VM-HT-275-15 Variants (Balloon Dia x Length): 2.75 x15 mm			
Model: VM-HT-275-16 Variants (Balloon Dia x Length): 2.75 x16 mm			
Model: VM-HT-275-18 Variants (Balloon Dia x Length): 2.75 x18 mm			
Model: VM-HT-275-20 Variants (Balloon Dia x Length): 2.75 x 20 mm			
Model: VM-HT-275-23 Variants (Balloon Dia x Length): 2.75 x 23 mm			
Model: VM-HT-275-25 Variants (Balloon Dia x Length): 2.75 x 25 mm			
Model: VM-HT-275-30 Variants (Balloon Dia x Length): 2.75 x 30mm			
Model: VM-HT-300-10 Variants (Balloon Dia x Length): 3.00 x 10 mm			
Model: VM-HT-300-12 Variants (Balloon Dia x Length): 3.00 x 12 mm			
Model: VM-HT-300-14 Variants (Balloon Dia x Length): 3.00 x 14 mm			
Model: VM-HT-300-15 Variants (Balloon Dia x Length): 3.00 x 15mm			
Model: VM-HT-300-16 Variants (Balloon Dia x Length): 3.00 x 16mm			
Model: VM-HT-300-18 Variants (Balloon Dia x Length): 3.00 x 18mm			

Model: VM-HT-300-20 Variants (Balloon Dia x Length): 3.00 x 20 mm			
Model: VM-HT-300-23 Variants (Balloon Dia x Length): 3.00 x 23 mm			
Model: VM-HT-300-25 Variants (Balloon Dia x Length): 3.00 x 25 mm			
Model: VM-HT-300-30 Variants (Balloon Dia x Length): 3.00 x 30 mm			
Model: VM-HT-325-10 Variants (Balloon Dia x Length): 3.25 x 10mm			
Model: VM-HT-325-12 Variants (Balloon Dia x Length): 3.25 x 12mm			
Model: VM-HT-325-14 Variants (Balloon Dia x Length): 3.25 x 14mm			
Model: VM-HT-325-15 Variants (Balloon Dia x Length): 3.25 x 15 mm			
Model: VM-HT-325-16 Variants (Balloon Dia x Length): 3.25 x 16 mm			
Model: VM-HT-325-18 Variants (Balloon Dia x Length): 3.25 x 18 mm			
Model: VM-HT-325-20 Variants (Balloon Dia x Length): 3.25 x 20mm			
Model: VM-HT-325-23 Variants (Balloon Dia x Length): 3.25 x 23mm			
Model: VM-HT-325-25 Variants (Balloon Dia x Length): 3.25 x 25mm			
Model: VM-HT-325-30 Variants (Balloon Dia x Length): 3.25 x 30 mm			
Model: VM-HT-350-10 Variants (Balloon Dia x Length): 3.50 x 10mm			
Model: VM-HT-350-12 Variants (Balloon Dia x Length): 3.50 x 12mm			
Model: VM-HT-350-14 Variants (Balloon Dia x Length): 3.50 x 14mm			
Model: VM-HT-350-15 Variants (Balloon Dia x Length): 3.50 x 15 mm			

Model: VM-HT-350-16 Variants (Balloon Dia x Length): 3.50 x 16 mm			
Model: VM-HT-350-18 Variants (Balloon Dia x Length): 3.50 x 18 mm			
Model: VM-HT-350-20 Variants (Balloon Dia x Length): 3.50 x 20mm			
Model: VM-HT-350-23 Variants (Balloon Dia x Length): 3.50 x 23mm			
Model: VM-HT-350-25 Variants (Balloon Dia x Length): 3.50 x 25mm			
Model: VM-HT-350-30 Variants (Balloon Dia x Length): 3.50 x 30 mm			
Model: VM-HT-375-10 Variants (Balloon Dia x Length): 3.75 x 10mm			
Model: VM-HT-375-12 Variants (Balloon Dia x Length): 3.75 x 12mm			
Model: VM-HT-375-14 Variants (Balloon Dia x Length): 3.75 x 14mm			
Model: VM-HT-375-15 Variants (Balloon Dia x Length): 3.75 x 15 mm			
Model: VM-HT-375-16 Variants (Balloon Dia x Length): 3.75 x 16 mm			
Model: VM-HT-375-18 Variants (Balloon Dia x Length): 3.75 x 18 mm			
Model: VM-HT-375-20 Variants (Balloon Dia x Length): 3.75 x 20mm			
Model: VM-HT-375-23 Variants (Balloon Dia x Length): 3.75 x 23mm			
Model: VM-HT-375-25 Variants (Balloon Dia x Length): 3.75 x 25mm			
Model: VM-HT-375-30 Variants (Balloon Dia x Length): 3.75 x 30 mm			
Model: VM-HT-400-10 Variants (Balloon Dia x Length): 4.00 x 10 mm			
Model: VM-HT-400-12 Variants (Balloon Dia x Length): 4.00 x 12 mm			

Model: VM-HT-400-14 Variants (Balloon Dia x Length): 4.00 x 14 mm			
Model: VM-HT-400-15 Variants (Balloon Dia x Length): 4.00 x 15mm			
Model: VM-HT-400-16 Variants (Balloon Dia x Length): 4.00 x 16mm			
Model: VM-HT-400-18 Variants (Balloon Dia x Length): 4.00 x 18mm			
Model: VM-HT-400-20 Variants (Balloon Dia x Length): 4.00 x 20 mm			
Model: VM-HT-400-23 Variants (Balloon Dia x Length): 4.00 x 23 mm			
Model: VM-HT-400-25 Variants (Balloon Dia x Length): 4.00 x 25 mm			
Model: VM-HT-400-30 Variants (Balloon Dia x Length): 4.00 x 30 mm			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/11/15	MIT/2023/P022	Initial issue