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

EC CERTIFICATE

No. 2019-MDD/QS-050

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 Is, IIa and IIb

Medical Devices for Urology
(for detailed list refer to Annex, pages 1 to 2)

manufactured by company

MED pro Medical B.V.
Vendelier 45 E, 3905PC, Veenendaal, The Netherlands

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 and found that it meets the requirements above. The quality system 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. 310343 and the Final protocol No. 310343/2019.

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 fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Digitally signed by Iarovoi Petru
Date: 2026.05.22 15:48:36 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

At Bratislava, on September 2nd, 2019

ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-050

issued for the company

MED pro Medical B.V.

Vendelier 45 E, 3905PC Veenendaal, The Netherlands

List of medical devices covered by the EC Certificate:

Product Description	Class	UMDNS Code
Ureteral Catheter	IIa	17683
PCN Catheter	IIa	17683
PCN Catheter with Needle	IIa	17683
PCN Catheter Set (PCN Catheter +FD+GW+IPN)	IIa	17683
Malecot Catheter	IIa	17683
Suprapubic Catheter	IIa	17683
Malecot Catheter Set (Malecot Catheter +FD+GW+IPN)	IIa	17683
Re-Entry Malecot Catheter	IIa	17683
CIC Catheter	IIa	17683
Tiemann Catheter	IIa	17683
Amplatz Sheath	IIa	10561
Ureteral Access Sheath	IIa	10561
Ureteral Balloon Dilation Catheter	IIa	11254
Ureteral Dilator Set	IIa	11254
Uretheral Dilator Set	IIa	11254
Amplatz Renal Dilator Set	IIa	11254
Ureteral Dilator	IIa	11254
Nottingham Dilator	IIa	11254
Urethral Filliform Dilator	IIa	11254
Meatal Dilator	Is	11254
Fascial Dilator Set	IIa	11254
Fascial Dilator	IIa	11254
Uretheral Dilator	IIa	11254
Renal Dilator	IIa	11254

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

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

At Bratislava, on September 2nd, 2019
Valid until May 26, 2024

ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-050

issued for the company

MED pro Medical B.V.

Vendelier 45 E, 3905PC Veenendaal, The Netherlands

List of medical devices covered by the EC Certificate:

Product Description	Class	UMDNS Code
Ball Electrode	IIb	15579
Cold Knife	IIb	15579
Colling's Knife	IIb	15579
TURP Electrode	IIb	15579
Bugbee Electrode	IIb	15579
Initial Puncture Needle	IIa	12727
Track finder bulb irrigator	IIa	14301
Stone Basket Nitinol	IIa	17574
Stone Basket Stainless Steel	IIa	17574
Stone Grasper	IIa	17574
Stent remover	IIa	16040
Guide Wire	IIa	11925
Double J stent /C/G/CG/S/SG/SC/SCG	IIa	16040
Loop Stent	IIa	16040
Endopylotomy stent	IIa	16040
Tumor Stent	IIa	16040
Mono J Stent	IIa	16040
Uretheral Stent	IIa	16040
Prostate Stent	IIa	16040
Long Pusher for Double J Stent	IIa	16040
Double J Stent Long Duro /C/G/CG/S/SG/SC/SCG	IIb	16040

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

At Bratislava, on September 2nd, 2019
Valid until May 26, 2024

MED pro Medical B.V.
Vendelier 45 E,
3905PC Veenendaal
The Netherlands

Attn. Andre ten Brinke / managing director

Our reference	***Contact person***	BRATISLAVA
MIT/2024/P081.1	Michal Tomin / +421 915 366 774	9.4.2024

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:

MED pro Medical B.V.
Vendelier 45 E,
3905PC Veenendaal
The Netherlands

SRN Number (if available): NL-MF-000024023

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.

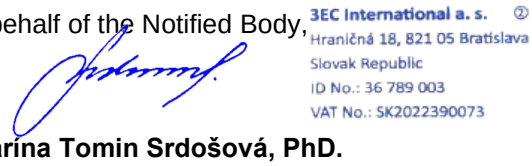
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date 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,



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
Double J Stent Long Duro **Trade name: Dobule J Stent Long Duro**	Class IIb excluding Class IIb implantable non-WET	Double J Stent Long Duro /C/G/CG/S/SG/SC/SCG was renamed to Double J Stent Long Duro	2019-MDD/QS-050 NB2265
Double J Stent **Trade name: Double J Stent** **Loop Stent** **Trade name:Loop stent** **Endopyelotomy Stent** **Trade name: Endopyelotomy Stent** **Tumor Stent** **Trade name:Tumor stent**	Class IIa	Double J stent /C/G/CG/S/SG/SC/SCG was renamed Double J Stent Endopylotomy stent was renamed Endopyelotomy Stent	2019-MDD/QS-050 NB2265
Ureteral Catheter **Trade name: Ureteral Catheter** **Mono J Sent** **Trade name:Mono J Stent**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Tiemann Catheter **Trade name: Tiemann Catheter**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Suprapubic Catheter **Trade name: Suprapubic Catheter**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Percutaneous Nephrostomy Catheter **Trade name: Percutaneous Nephrostomy Catheter**	Class IIa	PCN Catheter was renamed to Percutaneous Nephrostomy Catheter PCN Catheter with Needle was renamed to Percutaneous	2019-MDD/QS-050 NB2265

Percutaneous Nephrostomy Catheter with Needle **Trade name: Percutaneous Nephrostomy Catheter eith Needle** **Malecot Catheter** **Trade name: Malecot Catheter** **Re-Entry Malecot Catheter** **Trade name: Re-Entry Malecot Catheter**		Nephrostomy Catheter with Needle	
Guide Wire **Trade name: Guide Wire**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Initial Puncture Needle **Trade name: Initial Puncture Needle**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Amplatz Sheath **Trade name: Amplatz Sheath** **Ureteral Access Sheath** **Trade name: Ureteral Access Sheath**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Ureteral Balloon Dilation Catheter **Trade name: Ureteral Balloon Dilation Catheter** **Ureteral Dilator** **Trade name: Ureteral Dilator** **Models: Ureteral Dilator Set** **Nottinhgam Dilator** **Trade name: Nottingham Dilator**	Class IIa	N/A	2019-MDD/QS-050 NB2265
Urethral Filiform Dilator **Trade name: Urethral Filiform Dilator** **Meatal Dilator** **Trade name: Meatal Dilator** **Urethral Dilator** **Trade name:Urethral Dilator** **Alternative trade name: Urethral Dilator Set**	Class IIa	Urethral Filliform Dilator was renamed to Urethral Filiform Dilator Uretheral Dilator was renamed to Urethral Dilator Alternative trade name: Uretheral Dilator Set was renamed to Alternative trade name: Urethral Dilator Set	2019-MDD/QS-050 NB2265
Stone Basket Nitinol **Trade name: Stone Basket Nitinol** **Stone Basket Stainless Steel** **Trade name: Stone Basket Stainless Steel**	Class IIa	N/A	2019-MDD/QS-050 NB2265

Stone Grasper **Trade name:Stone Grasper**			
Ball Electrode **Trade name: Ball Electrode** **Cold Knife** **Trade name: Cold Knife** **Colling's Knife** **Trade name: Colling's Knife** **TURP Electrode** **Trade name: TURP Electrode** **Bugbee Electrode** **Trade name: Bugbee Electrode**	Class IIb excluding Class IIb implantable non-WET	N/A	2019-MDD/QS-050 NB2265
Percutaneous Nephrostomy Catheter Set (PCN Catheter+FD+GW+IPN) **Trade name: Percutaneous Nephrostomy Catheter Set (PCN Catheter+FD+GW+IPN)** **Malecot Catheter Set (Malecot Catheter+FD+GW+IPN)** **Trade name: Malecot Catheter Set (Malecot Catheter+FD+GW+IPN)** **Amplatz Renal Dilator Set** **Trade name:Amplatz Dilator Set**	Class IIa	PCN Catheter Set (PCN Catheter+FD+GW+IPN) was renamed to Percutaneous Nephrostomy Catheter Set (PCN Catheter+FD+GW+IPN)	2019-MDD/QS-050 NB2265
Urethral Stent **Trade name: Urethral Stent**	Class IIa	Uretheral Stent was substituted to Urethral Stent	2019-MDD/QS-050 NB2265

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
2024/4/8	MIT/2024/P081	Initial issue
2024/4/9	MIT/2024/P081.1	Administrative error – adding Urethral Stent to extension confirmation letter – MDR428_2024 application medical device was missing

3EC International

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

MED pro MEDICAL B.V.

Vendelier 45 E, 3905PC Veenendaal, The Netherlands

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, MANUFACTURE AND SALES OF MEDICAL DEVICES FOR UROLOGY, NEPHROLOGY AND ONCOLOGY

Certificate No.: M-0531/24 **Date of issuance: January 29th, 2024** **Original date of approval: February 20th, 2021**

This certificate is valid from **March 5th, 2024** to **March 4th, 2027** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.