

ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Общество с ограниченной ответственностью «Медицинские технологии и инновации»

наименование организации или фамилия, имя, отчество индивидуального предпринимателя, принявших декларацию о соответствии

Зарегистрирован(а) Межрайонной инспекцией Федеральной налоговой службы № 46 по городу Москве, дата регистрации 02.07.2018, ОГРН: 1187746633403

сведения о регистрации организации или индивидуального предпринимателя (наименование регистрирующего органа, дата регистрации, регистрационный номер)

Адрес: 125364, РОССИЯ, город Москва, улица Свободы, дом 50, строение 3, телефон: +7(495)6609346, +7(495)6609347

адрес, телефон, факс

в лице Генерального директора Черкаса Дмитрия Петровича

(должность, фамилия, имя, отчество руководителя организации, от имени которой принимается декларация)

заявляет, что Катетеры для радиологии с принадлежностями для катетеризации

I. Катетеры производства Bard Peripheral Vascular, Inc.:

- Opti-Plast XT-Xtra-thin PTA Catheters - Lowest Profile Performance.
- Opti-Plast XL-Xtra-large PTA Catheters - Lowest Profile Performance.
- Opti-Plast PTA Catheters.
- Ultraverse PTA Catheters
- Premium Nylon Platform.
- Bard Tru-Trac PTA Catheters.
- PAC Balloon Dilatation Catheters.
- CENTURION Balloon Dilatation Catheters.
- CONQUEST Balloon Dilatation Catheters.

II. Катетеры производства Angiomed GmbH & Co. Medizintechnik KG:

- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Cobra Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Divers Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Headhunter Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Hepatica Communis Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Hook Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Judkins Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Newton Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Pigtail Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Renal Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Shepered Hook Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Simmons Sidewinder Version.
- Angiomed Angiography Catheters, ANGIOFLEX, Non Braided Shaft, Straight Version.
- Angiomed Angiography Catheters, ANGIOPASS PLUS, Braided Shaft, Soft Tip, Hepatica Communis Version.
- Angiomed Angiography Catheters, ANGIOPASS PLUS, Braided Shaft, Soft Tip, Shepered Hook Version Angiomed.
- Angiography Catheters, ANGIOPASS PLUS, Braided Shaft, Soft Tip, Straight Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Cobra Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Divers Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Headhunter Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Judkins Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Multipurpose Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Pigtail Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Simmons Sidewinder Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Cobra Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Divers Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Headhunter Version.

- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Judkins Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Multipurpose Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Pigtail Version.
- Angiomed Angiography Catheters, ANGIOPASS, Braided Shaft, Soft Tip, Simmons Sidewinder Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Cobra Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Divers Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Hook Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Pigtail Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Radiopaque, Pigtail Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Radiopaque, Straight Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Renal Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Simmons Sidewinder Version.
- Angiomed Angiography Catheters, HIGH FLOW, Non Braided Shaft, Straight Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Bentson Hanafee Wilson Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Cobra Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Divers Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Headhunter Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Hook Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Mani Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Pigtail Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Renal Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Sheperd Hook Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Simmons Sidewinder Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Straight Version.
- Angiomed Angiography Catheters, MAXI SELECT, Non Braided Shaft, Vertebralis Version.
- Dacryography Catheter.
- Galactography Catheter.
- Mamillary Dilator.
- Sialography Catheter.
- PAT RAT, Aspiration Catheter, 1 Lumen.

III Катетеры производства Bard Access Systems:

- Broviac catheters.
- Leonard catheters.
- Hickman catheters.
- Hohn catheters.
- Groshong catheters.
- Groshong PICC's.
- Groshong midline catheters.
- Per-Q-Cath PICC.
- Per-Q-Cath Midline catheters.
- RadPICC catheters.
- ChronoFlex catheters Hickman Hemodialysis catheters.
- Soft-Cell catheters Opti-Flow catheters.
- Hemo-Glide catheters.
- Hemo-Split catheters.
- Flexxicon I and II catheters.
- Niagara catheters.
- Trialysis catheters.
- Vaccess Femoral catheters.
- Vaccess Subclavian jugular catheters.
- Vaccess jugular catheters.

- Arterial catheters DuPen Long term epidural catheters.
- AngioCath intravenous catheters.

IV. Принадлежности для катетеризации:

1. Проводники производства Angiomed GmbH & Co. Medizintechnik KG:

- Amplatz, Moveable Core, J Tip, Stainless Steel, PTFE Coated.
- Amplatz, Moveable Core, Straight, Stainless Steel, PTFE Coated.
- BARDSelct Range, Amplatz, Moveable Core, J Tip, Stainless Steel, PTFE Coated.
- BARDSelct Range, Amplatz, Moveable Core, Straight, Stainless Steel, PTFE Coated.
- BARDSelct Range, Standard, Fixed Core, Double Ended, J Tip, Stainless Steel, PTFE Coated.
- BARDSelct, Standard, Fixed Core, 3 Tip, Stainless Steel, PTFE Coated.
- BARDSelct Range, Standard, Fixed Core, Straight, Stainless Steel, PTFE Coated.
- BARDSelct Range, Standard, Moveable Core, J Tip, Stainless Steel, PTFE Coated.
- BARDSelct Range, Standard, Moveable Core, Straight, Stainless Steel, PTFE Coated.
- Bentson, Fixed Core, Straight, Stainless Steel, PTFE Coated.
- Heavy Duty, Fixed Core, Straight, Stainless Steel, PTFE Coated.
- Interventional Guide Wire, Fixed Core, Angled, Nitinol.
- Interventional Guide Wire, Fixed Core, J Tip, Nitinol.
- Interventional Guide Wire, Fixed Core, Straight, Nitinol.
- Portacaval Guiding Probe, Fixed Core, Straight, Nitinol.
- Soft Torque, WHITE WIRE, Fixed Core, Straight, Nitinol, PTFE Coated.
- Standard, Fixed Core, Double Ended, J Tip, Stainless Steel.
- Standard, Fixed Core, Double Ended, J Tip, Stainless Steel, PTFE Coated.
- Standard, Fixed Core, J Tip, Stainless Steel.
- Standard, Fixed Core, J Tip, Stainless Steel, PTFE Coated.
- Standard, Fixed Core, Straight, Stainless Steel.
- Standard, Fixed Core, Straight, Stainless Steel, PTFE Coated.
- Standard, Moveable Core, J Tip, Stainless Steel.
- Standard, Moveable Core, J Tip, Stainless Steel, PTFE Coated.
- Standard, Moveable Core, Straight, Stainless Steel.
- Standard, Moveable Core, Straight, Stainless Steel, PTFE Coated.
- Torque, BARDSelct Range, BLUE WIRE, Fixed Core, Angled, Nitinol, PTFE Coated.
- Ultra Torque, BARD Select Range, BLACK WIRE, Fixed Core, Angled, Nitinol, FEP Coated.
- Ultra Torque, BARD Select Range, BLACK WIRE, Fixed Core, Straight, Nitinol, FEP Coated.
- Ultra Torque, BARD Select Range, BLUE WIRE, Fixed Core, Straight, Nitinol, PTFE Coated.
- Ultra Torque, BLACK WIRE, Angled, Nitinol, FEP Coated.
- Ultra Torque, BLACK WIRE, Fixed Core, Straight, Nitinol, FEP Coated. Soft Torque, WHITE WIRE, Fixed Core, Angled, Nitinol, PTFE Coated.
- Torque, BLUE WIRE, Fixed Core, Angled, Nitinol, PTFE Coated.
- Torque, BLUE WIRE, Fixed Core, Straight, Nitinol, PTFE Coated.
- Guide Wires for Duodenal Stents (I).
- Litholapaxy Wires, J Curved.
- Litholapaxy Wires, J Curved, PTFE Coated.
- Litholapaxy Wires, Straight Version, PTFE Coated.
- Litholapaxy Wires, Straight Version PTC Guide Wires acc. to LUNDERQUIST.
- Safety Wires, Interventional, Straight Version.
- SCHULLER Exchange Wires, J Curved.
- SCHULLER Exchange Wires, J Curved, PTFE Coated.
- SCHULLER Exchange Wires, Straight Version.
- SCHULLER Exchange Wires, Straight Version, PTFE Coated.
- SCHULLER Litholapaxy Wires, Double Ended.
- SCHULLER Litholapaxy Wires, J Curved.
- SCHULLER Litholapaxy Wires, J Curved, PTFE Coated.
- SCHULLER Exchange Wires, J Curved, PTFE Coated.
- SCHULLER Exchange Wires, Straight Version.
- SCHULLER Exchange Wires, Straight Version, PTFE Coated.

- SCHULLER Litholapaxy Wires, Double Ended.
 - SCHULLER Litholapaxy Wires, J Curved.
 - SCHULLER Litholapaxy Wires, J Curved, PTFE Coated.
 - Special Exchange Wires, J Curved.
 - Special Exchange Wires, J Curved, PTFE Coated.
 - Special Exchange Wires, PTFE Coated Accessories Guide Wires, Pin Vise.
2. Проводники производства Bard Access Systems: - Guidewires.
3. Иглы производства Angiomed GmbH & Co. Medizintechnik KG:
- Angiography Needles. - Arterial Puncture Needle BARDSelct Range, Standard Cut.
 - Arterial Puncture Needle Standard Cut.
 - BARDSelct Range, Percutaneouse Entry Needle, Standard Cut.
 - CHIBA Needle Bevel Edged, 2 Part.
 - CHIBA Needle Bevel Edged, 2 Part, Graduated. - CHIBA Needle MS Cut, 2 Part.
 - CHIBA Needle MS Cut, 2 Part, Graduated.
 - Discography Set acc. to DR ZUBER. - Initial Puncture Needle Trocar Cut, 3 Part.
 - Initial Puncture Needle, Bevel Edged, 2 Part, Graduated, Model LORETTO.
 - Initial Puncture Needle, Bevel Edged, 2 Part, Model LORETTO.
 - Initial Puncture Needle, Bevel Edged, 2 Part, Model MERHEIM.
 - Initial Puncture Needle, Bevel Edged, 2 Part, Model OLDENBURG.
 - Initial Puncture Needle, Bevel Edged, 3 Part.
 - Initial Puncture Needle, MS Cut, 1 Part.
 - Initial Puncture Needle, MS Cut, 2 Part.
 - Initial Puncture Needle, MS Cut, 3 Part.
 - Initial Puncture Needle, MS Cut, 3 Part, Graduated.
 - Needle, Collagene Injection Needle, Bevel Edged, 1Part.
 - Needle, Hepatom Needle,
Type I.
 - Needle, Hepatom Needle,
Type II. - Percutaneouse Entry Needle modified acc. to Jantsch.
 - Percutaneouse Entry Needle, BARDSelct Range modified acc. to Jantsch.
 - Percutaneouse Entry Needle, Standard Cut.
 - Puncture Needle SUPER 4 modified ace. to Jantsch.
 - Puncture Needle SUPER 4, BARDSelct Range modified acc. to Jantsch.
 - Puncture Set acc. to STACKL.
 - SUPER 4 Needle, Arterial Puncture Needle.
 - SUPER 4 Needle, Puncture Needle, BARDSelct Range.
 - Initial Needle Set, 2 Part, PTFE Catheter.
 - Initial Puncture Needle, 2 Part, PTFE Catheter.
 - LEIGEN Needle Set, 2 Part, PTFE Catheter.
 - PTC initial Needle Set, 1 Part, PE Catheter.
 - Puncture Needle, 1 Part, PTFE Catheter.
 - SENGE Needle, 1 Part, High Flow Catheter.
 - Tumor Marking Set, Hook Wire.
4. Иглы производства Bard Access Systems:
- Hustead needles.
Winged infusion sets with non-coring needle.
 - Non-coring needles. - Hypodermic needles.
5. Интродюсеры производства Angiomed GmbH & Co. Medizintechnik KG:
- Introducer Set with Haemostatic Valve.
 - Introducer Set with Puncture Needle, Class IIa.
 - Percutaneous Introducer Set, Version A, Class IIa.
 - Percutaneous Introducer Set, Version B, Class IIa.
 - Special Introducer Set.
 - PAT RAT Introducer System, acc to STARCK.
6. Интродюсеры производства Bard Access Systems:
- Seldinger technique type introducers: Peel apart, Co-axial design.

- Sheath over-the-needle type introducers.
- Peel-apart micro introducers and excalibur introducers, Co-axial design (IV catheter).
- Over the guidewire type vessel dilators.

7. Принадлежности для ремонта катетеров производства Bard Access Systems:

- External catheter segments for Broviac and Hickman CV catheters.
- External catheter segments for Hickman and Leonard CV catheters.
- Hickman CV repair kit - extension legs.
- Groshong CV catheter repair kits for single lumen catheters.
- Groshong CV catheter repair kits for multi lumen catheters.
- Groshong CV catheter repair kit - extension legs.
- Per-Q-Cath PICC repair connectors.
- DuPen epidural catheter repair kits.

8. Порты производства Bard Access Systems:

- M.R.I. Low profile infusion ports.
- M.R.I. Implanted ports (plastic or titanium stem).
- M.R.I. Hard base implanted ports.
- M.R.I. Dual implanted ports (plastic or titanium).
- Titanium Low profile implanted ports (Slim Port).
- Titanium Dome implanted ports.
- Titanium implanted ports.
- SlimPort Rosenblatt dual low profile implanted ports.
- SlimPort ultra low profile M.R.I ports with titanium stem.
- X-Port low profile implanted ports.
- X-Port isp implanted ports.
- CathLink Standard Profile (SP) ports.
- CathLink Low Profile (LP) ports.
- CathLink Ultra-Low Profile (ULP) ports.

9. Шунты производства Angiomed GmbH & Co. Medizintechnik KG:

- Transjugular Intrahepatic Stent Shunt (TIPSS) Products, Porta Caval Set - Transjugular Intrahepatic Stent Shunt (TIPSS) Products, Porta Caval Guide Catheter, HIGHFLOW.
- Transjugular Intrahepatic Stent Shunt (TIPSS) Products, Porta Caval Guide Catheter, PTFE.
- Transjugular Intrahepatic Stent Shunt (TIPSS) Products, Porta Caval Introducer Set.
- Transjugular Intrahepatic Stent Shunt (TIPSS) Products, Porta Caval Needle.

10. Коннекторы производства Angiomed GmbH & Co. Medizintechnik KG:

- Contrast Media Connector, BARDSelect Range, Male and Female Luer Lock, Type B.
- Contrast Media Connector, BARDSelect Range, Male/Female Luer Lock, Type A.
- Contrast Media Connector, Male/Female Luer Lock, Type A.
- Contrast Media Connector, Male/Female Luer Lock, Type B.
- HIGH FLEX Connector, BARDSelect Range, Male to Female Luer Lock, Type A.
- HIGH FLEX Connector, BARDSelect Range, Type B.
- HIGH FLEX Connector, Male to Female Luer Lock, Type A. - HIGH FLEX Connector, Male to Female Luer Lock, Type B.
- Pressure Connector, BARDSelect Range, Male to Female Luer Lock.
- Pressure Connector, BARDSelect Range, Male to Female Luer Lock.
- Pressure Connector, Male and Female Luer Lock, Typ B.
- Pressure Connector, Male Luer Lock to Two Way Stopcock.
- Pressure Connector, Male to Female Luer Lock, Typ A.

11. Адаптеры производства Angiomed GmbH & Co. Medizintechnik KG: - Connecting Adapter, Female Luer Lock. - Connecting Adapter, Male Luer Lock. - Tuhey Borst Adapter.

12. Краники производства Angiomed GmbH & Co. Medizintechnik KG: - 2 Way Stopcock, Female Luer Lock. - 3 Way Stopcock, 2 Female Luer Lock.

13. Емкости производства Angiomed GmbH & Co. Medizintechnik KG: - Section Bag without Bacteria Filter. - Urine Bag with Bacteria Filter. - Urine Bag without Bacteria Filter. - Urine Leg Bag without Bacteria Filter.

14. Расщепляющая оболочка интродюсера производства Angiomed GmbH & Co. Medizintechnik KG: - Accessories Introducer Split Sheath.

15. Гемостатический клапан для катетеров производства Angiomed GmbH & Co. Medizintechnik KG: - Haemostatic Valve for Catheters, Diameter from 4-9F. - Haemostatic Valve for Catheters, Diameter from 5-8F.
16. Тромбоэкстраторы производства Angiomed GmbH & Co. Medizintechnik KG: - RAT Fragmentation Basket ace. to STARCK. - RAT Fragmentation Basket with Flexible Tip ace. to STARCK.
17. Дренажи производства Angiomed GmbH & Co. Medizintechnik KG: - Pericard Drainage Sets (Class III).
18. Фильтры производства Bard Peripheral Vascular, Inc.: - Simon Nitinol Filter.
19. Фильтры производства Bard Access Systems: - 0.22 Micron filter for use with epidural catheter.
20. Инфляторы производства Bard Peripheral Vascular, Inc.: - Max 30 Inflation Device. - Max 30i Inflation Device.
21. Стилеты производства Bard Access Systems: - Coated stylets Uncoated stylets Threader stylets.
22. Коннекторы производства Bard Access Systems: - Groshong Replacement Connectors.
23. Скальпели производства Bard Access Systems: - Scalpels.
24. Туннелеры производства Bard Access Systems: - Tunnelers.
25. Расширительные сетки производства Bard Access Systems: - Extension sets.
26. Зажимы производства Bard Access Systems: - Clamps.
27. Инъекционные насадки производства Bard Access Systems: - Injection caps.
28. Ножницы производства Bard Access Systems: - Scissors.
29. Отделители вен производства Bard Access Systems: - Vein picks.
30. Иглодержатели производства Bard Access Systems: - Needle holders.
31. Шприц-инжектор производства Bard Access Systems: - Syringes Flushing hubs.
32. Зажимы производства Bard Access Systems: - Forceps.

(наименование, тип, марка продукции, на которую распространяется декларация,

Серийный выпуск, Код ОКПД 2 - 32.50.50.000, Код ТН ВЭД 9018390000

сведения о серийном выпуске или партии (номер партии, номера изделий, реквизиты договора (контракта), накладная, код ОК 005-93 и (или) ТН ВЭД ТС или ОК 002-93 (ОКУН), номер и дата договора или контракта о поставке продукции

Изготовитель: "Бард Эксес Системс, Инк."/Bard Access Systems, Inc.,
 Адрес: СОЕДИНЕННЫЕ ШТАТЫ, 605 North 5600 West, Salt Lake City, Utah, 84116, USA.
 Место производства:

1. Bard Peripheral Vascular, Inc., 1625 West 3 Street, Tempe, AZ, 85281 USA;
2. Bard Access Systems, Inc., 605 North 5600 West Salt Lake City, Utah, 84116 USA;
3. Bard Reynosa S.A. De C.V. Blvd., Montebello Nol Parque Industrial Colonial Reynosa, Tamaulipas, Mexico;
4. Angiomed GmbH & Co. Medizintechnik KG, Wachhausstrasse 6, 76227 Karlsruhe, Germany

(наименование изготовителя, страны и т.п.)

соответствует требованиям ГОСТ Р 52770-2016, ГОСТ ISO 10993-1-2011, ГОСТ ISO 10993-4-2011, ГОСТ ISO 10993-5-2011, ГОСТ ISO 10993-6-2011, ГОСТ ISO 10993-10-2011, ГОСТ ISO 10993-11-2011, EN 556 -1-2011, ГОСТ Р ИСО 25539-2-2012

(обозначение нормативных документов, соответствие которым подтверждено

данной декларацией, с указанием пунктов этих нормативных документов, содержащих требования для данной продукции)

Декларация принята на основании: Протокола технических испытаний № 2018-341.2 от 30.07.2018 года, Испытательная лаборатория АО "НИИМТ", Аттестат аккредитации № РОСС RU.0001.517966 от 15.04.2015 года; Протокола токсикологических испытаний № 26952-4 от 30.07.2018 года, Лабораторный центр ООО «ЦКК ОНЦ», Аттестат аккредитации № РОСС RU.0001.21PK75 Регистрационного удостоверения на медицинское изделие № РЗН 2015/2425 от 25.02.2015 года, выдано Федеральной службой по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР).

(информация о документах, являющихся основанием

для принятия декларации)

Дата принятия декларации 31.07.2018

Декларация о соответствии действительна до 30.07.2021

М.П. _____
(подпись)

Черкас Дмитрий Петрович
(инициалы, фамилия)

Сведения о регистрации декларации о соответствии

Регистрационный номер RA.RU.11AB69, Орган по сертификации Общества с ограниченной ответственностью "ЛенСерт"

(наименование и адрес органа по сертификации, зарегистрировавшего декларацию)

адрес: 195027, РОССИЯ, город Санкт-Петербург, Пискаревский проспект, 2, корпус 3, литер А, офис 852, 854

Регистрационный номер декларации о соответствии РОСС US.AB69.D04486, от 31.07.2018

(дата регистрации и регистрационный номер декларации)

М. Вагер Галина Андреевна
(подпись, инициалы, фамилия руководителя органа по сертификации)

