

Registered with the Ministry of Justice of Russia on June 20, 2014, № 32823

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**MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION**

**ORDER № 737n  
October 14, 2013**

**ON THE APPROVAL OF THE ADMINISTRATIVE REGULATIONS  
OF THE FEDERAL SERVICE ON SURVEILLANCE IN HEALTHCARE  
FOR PROVIDING THE STATE SERVICE OF MEDICAL DEVICE REGISTRATION**

ConsultantPlus note:

The official text of the document contains a misprint: Government Decree № 1416 was published on Dec. 27, 2012 not on Dec. 24, 2012.

In accordance with Decrees № 1416 of the Government of the Russian Federation dated December 24, 2012 "On the approval of regulations of the state registration of medical devices" (Collection of the Legislation of the Russian Federation, 2013, № 1, art. 14) and № 373 dated May 16, 2011 "On the development and approval of administrative regulations for the performance of state functions and administrative regulations for providing state services" (Collection of the Legislation of the Russian Federation, 2011: № 22, art. 3169; № 35, art. 5092; 2012: № 28, art. 3908; № 36, art. 4903; № 50, art. 7070; № 52, art. 7507), I order:

1. the enclosed Administrative [Regulations](#) of the Federal Service on Surveillance in Healthcare for providing the state service of medical device registration to be approved;

2. Order № 735 of the Ministry of Health and Social Development of the Russian Federation dated October 30, 2006 "On the approval of the Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development for the performance of state functions in registering medical devices" (registered by the Ministry of Justice of the Russian Federation on November 30, 2006, registration № 8542) to be declared invalid.

Minister  
V.I. SKVORTSOVA

Approved  
by Order № 737n  
of the Ministry of Health  
of the Russian Federation  
dated October 14, 2013

**THE ADMINISTRATIVE REGULATIONS OF THE FEDERAL SERVICE  
ON SURVEILLANCE IN HEALTHCARE FOR PROVIDING THE STATE SERVICE  
OF MEDICAL DEVICE REGISTRATION**

I. General Provisions

Regulatory Subject of the Administrative Regulations

1. The Administrative Regulations of the Federal Service on Surveillance in Healthcare (hereafter referred to as Roszdravnadzor) for providing the state service of medical device registration (hereafter referred to respectively as Administrative Regulations and State Service) determines the terms and sequence of the administrative procedures (actions) of Roszdravnadzor carried out under the provision of state services, as well as the order of the interaction between the structural divisions of Roszdravnadzor and between its officers, and the interaction of Roszdravnadzor with applicants, other state authorities, local governments, agencies, and organizations while providing state services.

Applicants

2. Applicants for state services (hereafter referred to as applicants) are:

- 1) the developer of a medical device;
- 2) the manufacturer of a medical device;
- 3) an authorized representative of the manufacturer of a medical device <1>.

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<1> Section 8 of the Regulations for the State Registration of Medical Devices approved by Decree № 1416 by the Government of the Russian Federation dated December 27, 2012 (Collection of the Legislation of the Russian Federation, 2012: № 1, art. 14).

Requirements for the procedure of providing information  
regarding the State Service

3. Information about the procedure of providing the State Service is made available by Roszdravnadzor:

- 1) on the official Roszdravnadzor website: [www.roszdravnadzor.ru](http://www.roszdravnadzor.ru) (hereafter referred to as the official Roszdravnadzor site), including operating hours for receiving applicants and phone numbers for inquiries and consultations;
- 2) on the Common Government Services Portal of the Russian Federation: [www.gosuslugi.ru](http://www.gosuslugi.ru) (hereafter referred to as the Common Government Services Portal);
- 3) on bulletin boards in the Roszdravnadzor reception room;
- 4) by phone;
- 5) through the media.

Information about the procedure of providing the State Service can also be obtained from Roszdravnadzor at the following address:

4 Slavyanskaya Ploshchad, Building 1, Moscow, 109074.

Hours: M-T 9am - 1pm, 1:45pm - 6pm, F 9am - 1pm, 1:45pm - 4:45pm

Tel: +7 (495) 698-16-14; +7 (495) 698-45-38

Administration for the organization of the state control and registration of medical devices - Tel: +7 (499) 578-02-01; +7 (499) 578-02-99

4. Information about the federal executive authorities involved in providing the State Service:

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1) Federal Tax Service of Russia:

23 Neglinnaya Ul., Moscow, 127381

Tel: +7 (495) 913-00-09

Official site: [www.nalog.ru](http://www.nalog.ru)

Hours: M-T 9am - 1pm, 1:45pm - 6pm, F 9am - 1pm, 1:45pm - 4:45pm

2) Russian Federal Treasury:

9 Ilyinka Ul., Moscow, 109097

Tel: +7 (495) 984-12-97, +7 (495) 984-13-36

Official site: [www.roskazna.ru](http://www.roskazna.ru)

Hours: M-T 9am - 1pm, 1:45pm - 6pm, F 9am - 1pm, 1:45pm - 4:45pm

5. The following information and documents are posted on the Roszdravnadzor bulletin boards and on the official Roszdravnadzor site:

this document and a list of normative legal acts of the Russian Federation regulating the process of providing the State Service,  
hours for receiving applicants and phone numbers for inquiries (consultations),  
information about paying the state fee,  
samples of the application and the documents to be submitted for obtaining the State Service,  
procedure outline for obtaining a consultation,  
procedure outline for filing a complaint regarding the decisions, actions, or inactions of officials responsible for providing the State Service,  
information about the Common Government Services Portal.

6. The main requirements for the information provided to the applicants are:

- accuracy,
- clarity of the presentation,
- completeness,
- visual form,
- convenience and accessibility,
- efficiency.

The applicant can obtain information in person, in writing, and/or by phone.

## II. Standards for Providing the State Service

### Name of the State Service

7. The state service of medical device registration.

Name of the federal executive authority  
providing the State Service

8. The State Service is provided by Roszdravnadzor.

9. When providing the State Service, Roszdravnadzor cooperates with the following organizations:

- 1) the Federal Tax Service of Russia,
- 2) the Russian Federal Treasury.

10. It is prohibited to require the applicant to obtain services from government authorities and/or organizations other than those included in the list of services approved by the Government of the Russian Federation that are required for obtaining the State Service <1>.

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<1> Section 2 of the list of services that are required for providing state services by the federal executive authorities and are provided by organizations involved in providing state services, approved by Decree № 352 of the Government of the Russian Federation dated May 6, 2011 (Collection of the Legislation of the Russian Federation, 2011: № 20, art. 2829; 2012: № 14, art. 1655; № 36, art. 4922; 2013: № 33, art. 4382; № 52, art. 7207).

### The outcomes of requesting the State Service

11. The outcomes of requesting the State Service are:

- 1) the applicant is issued a notice regarding the state registration of the medical device and the registration certificate for the medical device;
- 2) the applicant is issued a notice refusing the state registration of the medical device;
- 3) the applicant is issued a notice regarding changes to the registration certificate for the medical device and a new registration certificate for the medical device. In addition, the previous registration certificate for the medical device is marked invalid;
- 4) the applicant is issued a duplicate registration certificate for the medical device;
- 5) the applicant is issued a notice regarding the cancellation of the state registration of the medical device.

### Period for providing the State Service

12. The state registration of a medical device may take up to 50 business days from the date a decision is made

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regarding the initiation of the registration process.

The duration of the clinical trials for a medical device is not included in the 50-day period.

The period of the suspension of the State Service is calculated from the date when Roszdravnadzor issues a permit for clinical trials of a medical device to be conducted until Roszdravnadzor resumes the state registration process.

13. Amending the registration certificate for a medical device may take up to 10 business days from the date the application for the modification and the documents specified in [Section 17](#) of the Administrative Regulations are accepted for processing.

14. The issuance of a duplicate registration certificate for a medical device may take up to 3 business days from the date the documents specified in [Section 18](#) of the Administrative Regulations are received.

#### List of normative legal acts regulating the process of providing the State Service

15. The list of normative legal acts regulating the process of providing the State Service:

1) Federal Law № 323-FZ dated November 21, 2011 "On the fundamentals of health protection in the Russian Federation" (Collection of the Legislation of the Russian Federation, 2011: № 48, art. 6724; 2012: № 26, art. 3442, p. 3446; 2013: № 27, art. 3459, p. 3477; № 30, art. 4038; № 39, art. 4883; № 48, art. 6165);

2) Federal Law № 210-FZ dated July 27, 2010 "On the organization of state and municipal services" (Collection of the Legislation of the Russian Federation, 2010: № 31, art. 4179; 2011: № 15, art. 2038; № 27, art. 3873, 3880; № 29, art. 4291; № 30, art. 4587; № 49, art. 7061; 2012: № 31, art. 4322; 2013: № 14, art. 1651; № 27, art. 3477, 3480; № 30, art. 4084; № 51, art. 6679; № 52, art. 6961, 7009, 6952);

3) Federal Law № 8-FZ dated February 9, 2009 № 8-FZ "On providing access to information about the activities of government bodies and local self-governing bodies" (Collection of the Legislation of the Russian Federation, 2009: № 7, art. 776; 2011: № 29, art. 4291; 2013: № 23, art. 2870; № 51, art. 6686; № 52, art. 6961);

4) Federal Law № 125-FZ dated October 22, 2004 "On the archives in the Russian Federation" (Collection of the Legislation of the Russian Federation, 2004: № 43, art. 4169; 2006: № 50, art. 5280; 2007: № 49, art. 6079; 2008: № 20, art. 2253; 2010: № 19, art. 2291; № 31, art. 4196; 2013: № 7, art. 611);

5) Tax Code of the Russian Federation (Part II) (Collection of the Legislation of the Russian Federation, 2000: № 32, art. 3340, 3341; 2001: № 1, art. 18; № 23, art. 2289; № 33, art. 3413, 3421, 3429; № 49, art. 4554, 4564; № 53, art. 5015, 5023; 2002: № 1, art. 4; № 22, art. 2026; № 30, art. 3021, 3027, 3033; № 52, art. 5132, 5138; 2003: № 1, art. 2, 5, 6, 8, 11; № 19, art. 1749; № 21, art. 1958; № 22, art. 2066; № 23, art. 2174; № 26, art. 2567; № 27, art. 2700; № 28, art. 2874, 2879, 2886; № 46, art. 4435, 4443, 4444; № 50, art. 4849; № 52, art. 5030; 2004: № 15, art. 1342; № 27, art. 2711, 2713, 2715; № 30, art. 3083, 3084, 3088; № 31, art. 3219, 3220, 3222, 3231; № 34, art. 3517, 3518, 3520, 3522, 3523, 3524, 3525, 3527; № 35, art. 3607; № 41, art. 3994; № 45, art. 4377; № 49, art. 4840; 2005: № 1, art. 9, 29, 30, 34, 38; № 21, art. 1918; № 23, art. 2201; № 24, art. 2312; № 25, art. 2427, 2428, 2429; № 27, art. 2707, 2710, 2713, 2717; № 30, art. 3101, 3104, 3112, 3117, 3118, 3128, 3129, 3130; № 43, art. 4350; № 50, art. 5246, 5249; № 52, art. 5581; 2006: № 1, art. 12, 16; № 3, p. 280; № 10, art. 1065; № 12, art. 1233; № 23, art. 2380, 2382; № 27, art. 2881; № 30, art. 3295; № 31, art. 3433, 3436, 3443, 3450, 3452; № 43, art. 4412; № 45, art. 4627, 4628, 4629, 4630; № 47, art. 4819; № 50, art. 5279, 5286; № 52, art. 5498; 2007: № 1, art. 7, 20, 31, 39; №

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13, art. 1465; № 21, art. 2461, 2462, 2463; № 22, art. 2563, 2564; № 23, art. 2691; № 31, art. 3991, 4013; № 45, art. 5416, 5417, 5432; № 46, art. 5553, 5554, 5557; № 49, art. 6045, 6046, 6071; № 50, art. 6237, 6245, 6246; 2008: № 18, art. 1942; № 26, art. 3022; № 27, art. 3126; № 30, art. 3577, 3591, 3598, 3611, 3614, 3616; № 42, art. 4697; № 48, art. 5500, 5503, 5504, 5519; № 49, art. 5723, 5749; № 52, art. 6218, 6219, 6227, 6236, 6237; 2009: № 1, art. 13, 19, 21, 22, 31; № 11, art. 1265; № 18, art. 2147; № 23, art. 2772, 2775; № 26, art. 3123; № 29, art. 3582, 3598, 3602, 3625, 3638, 3639, 3641, 3642; № 30, art. 3735, 3739; № 39, art. 4534; № 44, art. 5171; № 45, art. 5271; № 48, art. 5711, 5725, 5726, 5731, 5732, 5733, 5734, 5737; № 51, art. 6153, 6155; № 52, art. 6444, 6450, 6455; 2010: № 15, art. 1737, 1746; № 18, art. 2145; № 19, art. 229; № 21, art. 2524; № 23, art. 2797; № 25, art. 3070; № 28, art. 3553; № 31, art. 4176, 4198; № 32, art. 4298; № 40, art. 4969; № 45, art. 5750, 5756; № 46, art. 5918; № 47, art. 6034; № 48, art. 6247, 6248, 6249, 6250, 6251; № 49, art. 6409; 2011: № 1, art. 7, 9, 21, 37; № 11, art. 1492, 1494; № 17, art. 2311, 2318; № 23, art. 3262, 3265; № 24, art. 3357; № 26, art. 3652; № 27, art. 3881; № 29, art. 4291; № 30, art. 4563, 4575, 4583, 4587, 4593, 4597, 4596, 4606; № 45, art. 6332; № 47, art. 6608, 6609, 6610, 6611; № 48, art. 6729, 6731; № 49, art. 7014, 7015, 7016, 7017, 7037, 7061, 7063; № 50, art. 7347, 7359; 2012: № 10, art. 1164; № 14, art. 1545; № 18, art. 2128; № 19, art. 2281; № 24, art. 3066; № 25, art. 3268; № 26, art. 3447; № 27, art. 3587, 3588; № 29, art. 3980; № 31, art. 4319, 4322, 4334; № 41, art. 5526, 5527; № 49, art. 6747, 6748, 6749, 6750, 6751; № 50, art. 6958, 6968; № 53, art. 7578, 7584, 7596, 7603, 7604, 7607, 7619; 2013: № 9, art. 874; № 14, art. 1647; № 19, art. 2321; № 23, art. 2866, 2888, 2889; № 26, art. 3207; № 27, art. 3444; № 30, art. 4031, 4045, 4046, 4047, 4048, 4049, 4081, 4084; № 40, art. 5033, 5037, 5038, 5039; № 44, art. 5640, 5645, 5646; № 48, art. 6165; № 49, art. 6335; № 52, art. 6981, 6985);

6) Decree № 373 of the Government of the Russian Federation dated May 16, 2011 "On the development and approval of administrative regulations for the performance of state functions and administrative regulations for providing state services" (Collection of the Legislation of the Russian Federation, 2011: № 35, art. 5092; 2012: № 28, art. 3908; № 36, art. 4903; № 50, art. 7070; № 52, art. 7507; 2014: № 5, p. 506);

7) Decree № 1416 of the Government of the Russian Federation dated December 27, 2012 "On the approval of regulations of the state registration of medical devices" (Collection of the Legislation of the Russian Federation, 2013: № 1, art. 14; № 43, art. 5556);

8) Decree № 953 of the Government of the Russian Federation dated November 24, 2009 "On providing access to information about the activities of the Government of the Russian Federation and the federal bodies of executive power" (Collection of the Legislation of the Russian Federation, 2009: № 48, art. 5832; 2012: № 17 art. 2002; 2013: № 28, art. 3838; № 30, art. 4107);

9) Decree № 861 of the Government of the Russian Federation dated October 24, 2011 "On the federal government information systems which ensure the provision of the electronic form of state and municipal services (implementation of functions)" (Collection of the Legislation of the Russian Federation, 2011: № 44, art. 6274; № 49, art. 7284; 2013: № 45, art. 5807);

10) Decree № 323 of the Government of the Russian Federation dated June 30, 2004 "On the approval of the regulations about the Federal Service on Surveillance in Healthcare" (Collection of the Legislation of the Russian Federation, 2004: № 28, art. 2900; № 33, art. 3499; 2006: № 52, art. 5587; 2007: № 12, art. 1414; № 35, art. 4310; 2008: № 46, art. 5337; 2009: № 2, p. 244; № 6, p. 738; № 33, art. 4081; 2010: № 26, art. 3350; № 35, art. 4574; № 45, art. 5851; 2011: № 2, p. 339; № 14, art. 1935; 2012: № 1, Art. 171; № 20, art. 2528, № 26, art. 3531; 2013: № 20, art. 2477; № 45, art. 5822);

11) Decree № 352 of the Government of the Russian Federation dated May 6, 2011 "On the approval of the list of services that federal bodies of executive power are required to provide and are provided by organizations providing state services, and on the determination of service fees" (Collection of the Legislation of the Russian Federation, 2011: № 20, art. 2829; 2012: № 14, art. 1655; № 36, art. 4922; 2013: № 33, art. 4382; № 52, art. 7207);

12) Decree № 615 of the Government of the Russian Federation dated June 19, 2012 "On the approval of the Rules for the maintenance of the state register of medical devices and the organizations engaged in the

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production and manufacture of medical devices" (Collection of the Legislation of the Russian Federation, 2012: № 26, art. 3532);

13) Order № 4n of the Ministry of Health of the Russian Federation dated June 6, 2012 "On the approval of the nomenclature of medical devices" (registered by the Ministry of Justice of the Russian Federation on July 9, 2012, registration № 24852);

14) Order № 89n of the Ministry of Health of the Russian Federation dated August 15, 2012 "On the approval of the testing procedure for approving types of measuring instruments and also on the approval of the list of medical devices which are defined as measuring instruments by the state regulations for measurement uniformity and which are tested to confirm the measurement instrument type" (registered by the Ministry of Justice of the Russian Federation on December 25, 2012, registration № 26328);

15) Order № 1353n of the Ministry of Health of the Russian Federation dated December 21, 2012 "On the approval of the procedure for organizing and conducting an assessment of the quality, efficacy, and safety of a medical device" (registered by the Ministry of Justice of the Russian Federation on April 4, 2013, registration № 27991);

16) Order № 40-Pr/13 of the Federal Service on Surveillance in Healthcare dated January 16, 2013 "On the approval of form of a medical device registration certificate" (registered by the Ministry of Justice of the Russian Federation on February 25, 2013, registration № 27292), amended by the Federal Service on Surveillance in Healthcare on July 23, 2013 by Order № 3380-Pr/13 "On amendments to Order № 40-Pr/13 of the Federal Service on Surveillance in Healthcare dated January 16, 2013 'On the approval of the form of a medical device registration certificate'" (registered by the Ministry of Justice of the Russian Federation on September 10, 2013, registration № 29932);

17) Order № 4220-Pr/13 of the Federal Service on Surveillance in Healthcare dated August 19, 2013 "On the approval of the authorization form to conduct clinical trials of medical devices" (registered by the Ministry of Justice of the Russian Federation on September 10, 2013, registration № 29927).

Complete list of documents to be submitted by the applicant  
that are required for the State Service to be provided  
and other services required for the State Service to be provided  
in accordance with the normative legal acts

16. For the state registration of a medical device, the applicant must submit the following to Roszdravnadzor:
- 1) an application for the state registration of the medical device, in accordance with **Attachment № 1** to the Administrative Regulations;
  - 2) a copy of a document confirming the authority of the authorized representative of the manufacturer;
  - 3) regulatory documentation for the medical device;
  - 4) technical documentation for the medical device from the manufacturer;
  - 5) operational documentation for the medical device from the manufacturer, including the instruction manual for the medical device;
  - 6) photographs (at least 18 x 24 cm in size) with a general view of the medical device and any accessories required for using the medical device;
  - 7) the results of the technical tests of the medical device;
  - 8) the results of the toxicological studies (for medical devices which require contact with the human body);
  - 9) the results of the tests for approving the type of measuring instrument (for medical devices defined as measuring instruments by the state regulations for measurement uniformity <1>);

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<1> Order № 89n of the Ministry of Health of the Russian Federation dated August 15, 2012 "On the approval of the testing procedure for approving types of measuring instruments and also on the approval of the list of medical devices which

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are defined as measuring instruments by state regulations for measurement uniformity and which are tested to confirm the measurement instrument type" (registered by the Ministry of Justice of the Russian Federation on December 25, 2012, registration № 26328).

10) the documents listed in [Attachment № 2](#) to the Administrative Regulations.

17. To change the registration certificate, the applicant must submit the following:

- 1) an application to amend the registration certificate in accordance with [Attachment № 1](#) to the Administrative Regulations;
- 2) a copy of a document confirming the authority of the authorized representative of the manufacturer;
- 3) the number of the registration file;
- 4) the documents listed in [Attachment № 2](#) to the Administrative Regulations;
- 5) documents confirming any changes in the information about the applicant or the manufacturer of the medical device (if applicable);
- 6) if the name of the medical device has changed:  
regulatory documentation for the medical device;  
technical documentation from the manufacturer with the new name of the medical device;  
operational documentation from the manufacturer with the new name of the medical device, including the instruction manual with the new name of the medical device;  
photographs (at least 18 x 24 cm in size) with a general view of the medical device and any accessories required for using the medical device.

18. To obtain a duplicate registration certificate, the applicant must submit the following:

- 1) an application for a duplicate registration certificate in accordance with [Attachment № 3](#) to the Administrative Regulations;
- 2) if the registration certificate is damaged, the damaged certificate must be submitted with the application for a duplicate registration certificate.

19. If the original documents specified in [Sections 16 - 17](#) of the Administrative Regulations are in a foreign language, they must be submitted with a certified Russian translation.

20. The application and the documents specified in [Sections 16 - 18](#) of the Administrative Regulations must be submitted by the applicant to Roszdravnadzor in person, by registered mail (with return receipt requested) including a list of contents, or by e-mail with an electronic signature or the Common Government Services Portal.

Roszdravnadzor is not allowed to require the applicant to provide any information or documents not specified in [Sections 16 - 18](#) of the Administrative Regulations.

Complete list of documents to be submitted by the applicant  
which are provided by other state authorities  
involved in providing the State Service  
in accordance with the normative legal acts

21. The following information provided by the state authorities listed is required for the State Service to be provided:

- 1) The Federal Tax Service of Russia: information about the applicant from the Unified State Register of Legal Entities;
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2) The Russian Federal Treasury: verification of the payment of the state fee for providing the State Service.

22. It is the responsibility of the applicant to submit the information specified in [Section 21](#) of the Administrative Regulations.

23. The following cannot be required of the applicant:

- 1) the submission of documents and/or information or the implementation of actions which are not stipulated by the normative legal acts of the Russian Federation regulating relations arising in the process of providing the State Service;
- 2) the submission of documents and/or information which are, in accordance with the regulations of the Russian Federation, available to other state agencies involved in providing the State Service and which may be obtained by interagency information exchange.

Complete list of the grounds for refusing  
to accept the documents necessary for providing the  
State Service

24. There are no grounds for refusing to accept the documents required for the State Service to be provided.

Complete list of the grounds for suspending  
or refusing to provide the State Service

25. A reason for suspending the State Service is Roszdravnadzor granting permission to conduct clinical trials of a medical device.

26. The grounds for refusing the State Service are:

- 1) a conclusion that it is not possible to conduct clinical trials of a medical device;
- 2) the results of the assessment of the quality, efficacy, and safety of a medical device show that the quality and/or efficacy and/or the safety of the medical device do not meet the standards, and/or that the medical device is found to have an associated risk of adverse health effects for patients and/or medical staff that exceeds its efficacy;
- 3) information about the payment of the service fee has not been provided.

The list of services that are required for the State Service to be provided  
including information about the document(s) issued by  
organizations involved in providing the State Service

27. An assessment of the quality, efficacy, and safety of a medical device is required for the State Service to be provided.

Documents issued by the organizations involved in providing the State Service:

- decision concerning the possibility (or impossibility) of conducting clinical trials of a medical device;
  - results of the quality, efficacy, and safety assessment of a medical device.
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The procedure, amount, and grounds for charging the state fee  
or other fees for providing the State Service

28. The state fee in the amount specified in Article 333.32.2 of the Tax Code of the Russian Federation must be paid for the State Service to be provided:

- 1) for the state registration of a medical device - 6,000 rubles;
- 2) for amending the registration certificate of a medical device - 1,200 rubles;
- 3) for a duplicate registration certificate of a medical device - 1,200 rubles.

The procedure, amount, and grounds  
for charging a fee for providing services that are required  
for the State Service to be provided, including how the fee is calculated

29. The state fee in the amount specified in Article 333.32.2 of the Tax Code of the Russian Federation must be paid for the assessment of the quality, efficacy, and safety of a medical device:

- 1) for the assessment of the quality, efficacy, and safety of a medical device (depending on the class of the potential risk of its use in accordance with the nomenclature classification of medical devices approved by the federal executive authority responsible for drafting and implementing national policy and legal regulations regarding healthcare):  
Class 1 - 40,000 rubles;  
Class 2a - 54,000 rubles;  
Class 2b - 73,000 rubles;  
Class 3 - 98,000 rubles.

Maximum waiting time in line when submitting a request  
for the State Service and when receiving the results of the State Service

30. The maximum waiting time in line for the applicant (or the applicant's representative) when submitting the documents required for the State Service to Roszdravnadzor in person should not exceed 15 minutes.

31. The maximum waiting time in line when the applicant (or the applicant's representative) receives the documents which are the result of the State Service from Roszdravnadzor should not exceed 15 minutes.

Duration and procedure of the registration of the applicant's request  
for the State Service to be provided, including  
electronic requests.

32. Documents that are in accordance with [Section 20](#) of the Administrative Regulations submitted by the applicant to Roszdravnadzor in person or electronically should be registered within 1 business day from the submission date.

33. The administrative procedures that Roszdravnadzor officials are responsible for when documents (including electronic ones) are submitted to Roszdravnadzor are receiving and registering the documents, making a list of the documents that includes the date when the application was submitted and when the documents were accepted, making a copy of the document list, and providing the applicant with a copy of the document list on the

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date the documents are submitted if the documents are submitted in person or providing the applicant with a copy of the document list by registered mail (with a return receipt) or electronically if the documents were not submitted in person.

The requirements for the premises where the State Service is provided;  
the requirements for the reception areas and waiting rooms for the applicants;  
the requirements for the placement and design of the visual,  
textual, and multimedia information on the procedure  
of providing the State Service

34. The premises intended for providing the State Service should have all necessary equipment, office supplies, furniture, air conditioning, a cloakroom, telephones, computers with Internet access and printers, as well as offer access to hard copies or electronic forms of documents (information).

35. The visual, textual, and multimedia information specified in [Section 5](#) of the Administrative Regulations about the procedure of providing the State Service is displayed on bulletin boards or information terminals (that are conveniently located), as well as on the Common Government Services Portal and the official Roszdravnadzor site.

36. The visual, textual, and multimedia information about the procedure of providing the State Service should be designed to be clearly understandable by the applicants.

37. The entrance to the premises and movement within the premises where the State Service is provided should not be obstructed nor create difficulties for people with disabilities.

#### Indicators of availability and quality of the State Service

38. The indicators of the availability and quality of the State Service are:

- 1) access to information about the procedure and duration of the State Service and the procedure for filing complaints regarding the actions (or inactions) of Roszdravnadzor officers;
- 2) compliance with the standards for providing the State Service;
- 3) the absence of complaints from applicants regarding the actions (or inactions) of Roszdravnadzor officers who provide the State Service;
- 4) the completeness and relevance of the information concerning the procedure for providing the State Service;
- 5) allowing the application and other documents required for the State Service to be submitted electronically;
- 6) providing information concerning the procedure of the State Service (including through the use of information and communication technologies).

### III. Structure, Sequence, Duration, and Implementation Requirements of Administrative Procedures (Actions), Including Specifications for Electronic Implementation

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#### List of administrative procedures

39. The following administrative procedures are implemented for providing the State Service:
- 1) receiving and registering the application and documents for the state registration of a medical device; initiating the process for the state registration of a medical device;
  - 2) outlining the specifications for the assessment of the quality, efficacy, and safety of a medical device; analyzing the results of the assessment and deciding if clinical trials of a medical device can be conducted;
  - 3) resuming the state registration of a medical device;
  - 4) evaluating the conclusions of the expert institution to determine the compliance with the specifications for the assessment of the quality, efficacy, and safety of a medical device and making a decision regarding the state registration of a medical device;
  - 5) amending the registration certificate for a medical device;
  - 6) issuing a duplicate registration certificate for a medical device;
  - 7) cancelling the state registration of a medical device.
40. A diagram of the process of providing the State Service is shown in [Attachment № 6](#) to the Administrative Regulations.
41. The heads of the Roszdravnadzor departments providing the State Service in accordance with the administrative regulations for state services maintain a documented record of each stage of the administrative procedure.

Receiving and registering the application and documents  
for the state registration of a medical device;  
deciding to initiate the process for the state registration  
of a medical device

42. The administrative procedure of "receiving and registering the application and documents for the state registration of a medical device; deciding to initiate the process for the state registration of a medical device" is initiated after the applicant submits an application and the documents specified in [Section 16](#) and [Section 20](#) of the Administrative Regulations to Roszdravnadzor for the state registration of a medical device using the Common Government Services Portal.
43. When the application for the state registration of a medical device and the documents specified in [Section 16](#) of the Administrative Regulations are accepted by Roszdravnadzor, the Roszdravnadzor officer makes a list of the documents that includes the date when the application was submitted and when the documents were accepted, makes a copy of the document list, and provides the applicant with the copy of the document list on the date the documents are submitted if the documents are submitted in person or provides the applicant with a copy of the document list by registered mail (with a return receipt) or electronically (with an electronic signature) if the documents were not submitted in person.
44. The official responsible for providing the State Service appoints an officer of the staff of the department performing the state registration of medical devices to be the executive in charge (hereafter referred to as the executive in charge) no later than the next business day after the date the registration application and the documents specified in [Section 16](#) of the Administrative Regulations are submitted.

The last name, first name, patronymic (if available), and phone number of the executive in charge must be

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provided at the applicant's written or oral request and be available to the applicant on the official Roszdravnadzor site.

45. The executive in charge verifies the completeness and accuracy of the submitted documents by comparing the information contained in the documents with the information obtained through interagency exchange within 3 business days from the date the application for the state registration of a medical device and the documents specified in [Section 16](#) of the Administrative Regulations are submitted.

46. As a part of the administrative procedure of receiving and registering the application and documents for the state registration of a medical device and making a decision to initiate the state registration of a medical device, the executive in charge creates and sends interagency requests to the authorities involved in providing the State Service within 3 business days from the date the application and the documents specified in [Section 16](#) of the Administrative Regulations are submitted to the executive in charge in order to obtain the information required for the State Service.

The information required for the State Service can also be provided electronically using the unified interagency system of electronic interaction and the regional interagency system of electronic interaction.

47. An interagency request for the information specified in [Section 21](#) of the Administrative Regulations must contain the following information:

- 1) verification that the authority making the interagency request is Roszdravnadzor;
- 2) the name of the state authority receiving the interagency request;
- 3) the name of the state service which requires the requested information and/or documents;
- 4) the provisions of the Administrative Regulations and other normative legal acts and references to the relevant legal acts which state that the requested document(s) and/or information required for the State Service must be indicated;
- 5) the information required for providing the document(s) and/or information established by the Administrative Regulations, as well as the information required for providing such documents and/or information established by the normative legal acts;
- 6) contact information for responding to the interagency request;
- 7) the date the interagency request was submitted;
- 8) the last name, first name, patronymic, position, telephone number, and/or e-mail address of the executive in charge.

48. In the event that an application for the state registration of a medical device is filled out incorrectly and/or contains false information or not all of the documents specified in [Section 16](#) of the Administrative Regulations are submitted, the applicant receives a notice in person, by certified mail (with return receipt requested), or electronically (with an electronic signature) from Roszdravnadzor indicating the issues that should be corrected within a 30-day period.

49. When an application for the state registration of a medical device and all documents specified in [Section 16](#) of the Administrative Regulations are submitted in full or when the issues specified in the notice are eliminated within 30 days, the executive in charge assigns a number to the registration file within 3 business days, which indicates the initiation of the state registration of the medical device.

The number of the registration file consists of a number assigned during the registration of the application and documents in accordance with [Section 16](#) of the Administrative Regulations and a serial number assigned sequentially following a continuous numbering format regardless of the calendar year when the application and

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documents were submitted.

50. In the event that the issues specified in the notice are not eliminated within the 30-day period, the executive in charge prepares a letter to be signed by the head of Roszdravnadzor stating the reason(s) for the return of the application for the state registration of a medical device and the submitted documents.

Outlining the specifications for the assessment  
of the quality, efficacy, and safety of a medical device;  
analyzing the results of the assessment  
and deciding if clinical trials of a medical device can be conducted

51. The administrative procedure of "outlining the specifications for the assessment of the quality, efficacy, and safety of a medical device; analyzing the results of the assessment and deciding if clinical trials of a medical device can be conducted" is performed after the decision to initiate the state registration of a medical device is made by Roszdravnadzor.

52. Roszdravnadzor prepares and outlines specifications for the assessment (to be carried out in stages) of the quality, efficacy, and safety of a medical device that are issued to the Federal State Budgetary Institution (hereafter referred to as the expert institution) under the authority of Roszdravnadzor within 3 business days after the decision to initiate the state registration of a medical device <1>.

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<1> Order № 1353n of the Ministry of Health of the Russian Federation dated December 21, 2012 "On the approval of the procedure for organizing and conducting an assessment of quality, efficacy, and safety of a medical device" (registered by the Ministry of Justice of the Russian Federation on April 4, 2013, registration № 27991).

53. The following procedures are performed by Roszdravnadzor within 5 business days of receiving the decision concerning the possibility (or impossibility) of conducting clinical trials of a medical device from the expert institution:

- 1) an analysis of the conclusions to determine the compliance with the specifications for the assessment of the quality, efficacy, and safety of the medical device;
- 2) an order made by Roszdravnadzor either granting permission to conduct clinical trials of the medical device or refusing the state registration of the medical device; the applicant is notified of the decision;
- 3) the applicant is issued (in person, by registered mail with return receipt, or electronically with an electronic signature) the authorization document approved by Order № 4220-Pr/13 of Roszdravnadzor dated August 19, 2013 "On the approval of the authorization form to conduct clinical trials of medical devices" (registered by the Ministry of Justice of the Russian Federation on September 10, 2013, registration № 29927) which grants the applicant permission to conduct clinical trials of the medical device and this information is recorded in the register of permits to conduct clinical trials of a medical device; or the applicant is issued a notice denying the state registration of the medical device which indicates the reasons for the refusal.

54. A conclusion from the expert institution that clinical trials cannot be conducted is a reason for refusing the state registration of a medical device.

55. Roszdravnadzor suspends the state registration of a medical device when clinical trials of the medical device are to be conducted until Roszdravnadzor decides to resume the state registration process.

56. The applicant should notify Roszdravnadzor about the clinical trials of a medical device within 5 business days

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from the beginning of the trials.

57. At the end of the clinical trials, the applicant submits an application to resume the state registration of a medical device along with the results of the clinical trials.

58. The following documents should be included in the registration file for a medical device: copies of the specifications for the assessment of the quality, efficacy, and safety of the medical device, copies of the decision to allow clinical trials of the medical device to be conducted or the decision to refuse the state registration of the medical device, and copies of the notices to the applicant, including copies of the authorization document for conducting clinical trials of the medical device or the notification of the refusal of the state registration of the medical device.

#### Resuming the state registration of a medical device

59. The administrative procedure of "resuming the state registration of a medical device" is performed after an application in accordance with [Attachment № 4](#) to the Administrative Regulations for resuming the state registration of a medical device is submitted to Roszdravnadzor by the applicant in person or using the Common Government Services Portal.

60. Roszdravnadzor makes a decision about resuming the state registration of a medical device within 2 business days of receiving the application to resume the state registration of the medical device and the results of the clinical trials of the medical device.

After making the decision, Roszdravnadzor sends the results of the clinical trials of the medical device submitted by the applicant to the expert institution within 2 business days.

61. The application for resuming the state registration of a medical device and the results of the clinical trials of the medical device should be added to the registration file of the medical device.

#### Analyzing the conclusions of the expert institution to determine the compliance with the specifications for the assessment of the quality, efficacy, and safety of a medical device and making a decision regarding the state registration of a medical device

62. The administrative procedure of "analyzing the conclusions of the expert institution to determine the compliance with the specifications for the assessment of the quality, efficacy, and safety of a medical device and making a decision regarding the state registration of a medical device" is performed after Roszdravnadzor receives the conclusions of the results of the assessment of the quality, efficacy, and safety of a medical device from the expert institution.

63. The following procedures are performed by Roszdravnadzor within 10 business days of receiving the conclusions specified in [Section 62](#) of the Administrative Regulations:

- 1) an analysis of the conclusions to determine the compliance with the specifications for the assessment of the quality, efficacy, and safety of a medical device;
  - 2) a decision is made by Roszdravnadzor either allowing the state registration of the medical device or refusing the state registration of the medical device; the applicant is notified of the decision;
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3) the applicant is issued (in person, by registered mail with a return receipt, or electronically with an electronic signature) a registration certificate or a notice denying the state registration of the medical device, which indicates the reasons for the refusal.

64. The registration certificate of a medical device is issued in perpetuity <1>.

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<1> Section 6 of the Regulations for the state registration of medical devices, approved by Decree № 1416 of the Government of the Russian Federation dated December 27, 2012.

65. The expert institution concluding that the results of the assessment of quality, efficacy, and safety of a medical device show that the quality and/or efficacy and/or the safety of a medical device do not meet the standards, and/or that a medical device is found to have an associated risk of adverse health effects for patients and/or medical staff that exceeds its efficacy are grounds for the decision of Roszdravnadzor to refuse the state registration of a medical device.

66. Roszdravnadzor records the information in the state register of medical devices and the organizations engaged in the production and manufacture of medical devices in accordance with the regulations of the Government of the Russian Federation within 1 working day after the decision is made concerning the state registration of a medical device <1>.

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<1> Decree № 615 of the Government of the Russian Federation dated June 19, 2012 "On the approval of the Rules for the maintenance of the state register of medical devices and the organizations engaged in the production and manufacture of medical devices".

67. The following documents should be included in the registration file for a medical device: the results of the assessment of the quality, efficacy, and safety of a medical device, copies of the decision to allow or refuse the state registration of a medical device, notices to the applicant, and a second copy of the registration certificate or a copy of the notice of the refusal of the state registration of a medical device.

#### Amending the registration certificate of a medical device

68. The administrative procedure of "amending the registration certificate of a medical device" is performed after the applicant submits an application for amending the registration certificate of a medical device and the documents and information specified in [Section 17](#) and [Section 20](#) of the Administrative Regulations to Roszdravnadzor using the Common Government Services Portal.

69. The registration certificate is amended in the following cases:

- 1) if the information about the applicant changes, including:
  - the reorganization of the legal entity;
  - the name of the legal entity (full name and (if available) abbreviated name, including the company name);
  - the address (location);
- 2) change of address of the manufacturer of the medical device;
- 3) change of name of the medical device (if the properties and characteristics that affect the quality, efficacy, and safety have not changed).

70. When the application for amending the registration certificate of a medical device and the documents specified in [Section 17](#) of the Administrative Regulations are accepted by Roszdravnadzor, a Roszdravnadzor

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officer makes a list of the documents that includes the date when the application was submitted and when the documents were accepted, makes a copy of the document list, and provides the applicant with the copy of the document list on the date the documents are submitted if the documents are submitted in person or provides the applicant with a copy of the document list by registered mail (with a return receipt) or electronically (with an electronic signature) if the documents were not submitted in person.

71. Roszdravnadzor verifies the completeness and accuracy of the submitted documents by comparing the information contained in the documents with the information obtained through interagency exchange within 3 business days from the date the application for amending the registration certificate of the medical device and the documents specified in [Section 17](#) of the Administrative Regulations are submitted.

72. The creation and submission of interagency requests to the authorities providing the State Service are performed in accordance with [Section 46](#) and [Section 47](#) of the Administrative Regulations.

73. In the event that an application for amending the registration certificate of a medical device is submitted without all of the documents specified in [Section 17](#) of the Administrative Regulations and/or the application contains false information, the applicant receives a notice in person, by certified mail (with return receipt requested), or electronically (with an electronic signature) from Roszdravnadzor indicating the issues that should be corrected within a 30-day period.

74. When an application for amending the registration certificate of a medical device and all of the documents specified in [Section 17](#) of the Administrative Regulations are submitted correctly, Roszdravnadzor decides to process the application and the documents or return them with a notice indicating the reason for the return within 3 business days.

75. In the event that the issues specified in the notice are not eliminated within the 30-day period, Roszdravnadzor returns the application for amending the registration certificate of a medical device and the submitted documents along with a notice indicating the reason for the return.

76. The registration certificate of a medical device is amended by Roszdravnadzor within 10 business days after the decision is made to process the application for amending the registration certificate of a medical device and the documents specified in [Section 17](#) of the Administrative Regulations.

77. The period for making a decision to amend the registration certificate of a medical device is calculated from the date when the application for amending the registration certificate of a medical device and the documents specified in [Section 17](#) of the Administrative Regulations are correctly submitted to Roszdravnadzor.

78. The following procedures to amend the registration certificate of a medical device are performed by Roszdravnadzor within 10 business days:

- 1) an order is made by Roszdravnadzor regarding the decision to amend the registration certificate of a medical device;
- 2) the applicant is issued a written notice regarding the decision (in person, by registered mail with a return receipt, or electronically with an electronic signature);
- 3) the applicant is issued a registration certificate of a medical device (in person, by registered mail with a return receipt, or electronically with an electronic signature).

79. If Roszdravnadzor decides to amend the registration certificate of a medical device, the applicant is issued a new registration certificate; the previous registration certificate, which should be submitted in person, by

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registered mail (with a return receipt), or electronically (with an electronic signature), is marked as invalid (with the date).

80. Roszdravnadzor records the information in the state register of medical devices and the organizations engaged in the production and manufacture of medical devices in accordance with the regulations of the Government of the Russian Federation within 1 working day after the decision is made concerning the registration certificate of a medical device being amended <1>.

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<1> Decree № 615 of the Government of the Russian Federation dated June 19, 2012 "On the approval of the Rules for the maintenance of the state register of medical devices and the organizations engaged in the production and manufacture of medical devices".

81. The following documents should be included in the registration file for a medical device: the application for amending the registration certificate of a medical device, the documents specified in [Section 17](#) of the Administrative Regulations, copies of the decision to amend the registration certificate of the medical device, notices to the applicant, and a second copy of the registration certificate of the medical device.

#### Issuing a duplicate of the registration certificate of a medical device

82. The administrative procedure of "issuing a duplicate of the registration certificate of a medical device" is performed after the applicant submits an application for a duplicate of the registration certificate of a medical device and the documents specified in [Section 18](#) of the Administrative Regulations to Roszdravnadzor.

83. Roszdravnadzor issues a duplicate of the registration certificate of a medical device within 3 business days after receiving the documents specified in [Section 18](#) of the Administrative Regulations; the new registration certificate is marked with "duplicate" and "the original registration certificate is invalid" and is issued to the applicant in person or by registered mail (with a return receipt).

84. The following documents should be included in the registration file for a medical device: the application for a duplicate registration certificate of a medical device, the documents specified in [Section 18](#) of the Administrative Regulations, and a copy of the duplicate registration certificate of the medical device.

#### Cancelling the state registration of a medical device

85. Roszdravnadzor cancels the state registration of a medicinal device in the following cases:

- 1) an applicant submits an application for the cancellation of the state registration of a medical device in accordance with [Attachment № 5](#) to the Administrative Regulations;
- 2) a court decision finding that using the medical device results in an intellectual property rights violation and/or a trademark (or other means of identification) infringement;
- 3) information confirming that there is an associated risk of adverse health effects for patients and/or medical staff when using the medical device that is provided by the federal authorities responsible for the state control of the usage of medical devices authorized by the Government of the Russian Federation <1>.

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<1> Section 57 of the Regulations for the state registration of medical devices, approved by Decree № 1416 of the Government of the Russian Federation dated December 27, 2012.

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86. The executive in charge appointed by the head of the department providing the state registration of a medical device examines the information and reasons specified for requesting the cancellation of the state registration of a medical device within 1 business day from the date the application for cancelling the state registration of a medical device is submitted to Roszdravnadzor.

87. The executive in charge prepares a draft order for cancelling the state registration of a medical device which is initialed by the head of the department responsible for providing the state registration of medical devices and is signed by the head of Roszdravnadzor within 5 business days from the date the application for cancelling the state registration of a medical device is submitted to Roszdravnadzor.

88. The executive in charge appointed by the head of the department responsible for providing the state registration of medical devices prepares a draft order to cancel the state registration of a medical device that is initialed by the head of department and signed by the head of Roszdravnadzor within 5 business days from the date when a judicial act concerning an intellectual property rights violation and/or a trademark (or other means of identification) infringement takes effect in accordance with the legislation of the Russian Federation and is submitted to Roszdravnadzor.

89. The executive in charge prepares a draft order to cancel the state registration of a medical device that is initialed by the head of the department responsible for providing the state registration of medical devices signed by the head of Roszdravnadzor within 5 business days from the date the information confirming that there is an associated risk of adverse health effects for patients and/or medical staff when using the medical device that is provided by the federal authorities responsible for the state control of the usage of medical devices authorized by the Government of the Russian Federation is submitted to Roszdravnadzor.

90. The executive in charge records the information in the state register of medical devices and the organizations engaged in the production and manufacture of medical devices within 1 business day after the order to cancel the state registration of a medical device is signed.

#### IV. Methods of Controlling the Process of Providing the State Service

The procedure for monitoring and ensuring the compliance of those responsible with the provisions of the Administrative Regulations and other normative legal acts establishing the requirements for providing the State Service

91. The head of Roszdravnadzor and the officers of Roszdravnadzor responsible for controlling how the State Service is provided monitor those responsible for providing the State Service to ensure their compliance with the regulations outlined by the administrative procedures for providing the State Service, the provisions of the Administrative Regulations, and other normative legal acts of the Russian Federation by conducting inspections and by conducting internal audits regarding the effectiveness of providing the State Service (hereafter referred to as the inspections).

92. The inspections of the efficiency and quality of how the State Service is provided include audits, identifying and eliminating any violations against the rights of an applicant, evaluations, decision-making, and preparing responses to the applicants who submitted complaints regarding the action or inaction of the officers of Roszdravnadzor responsible for providing the State Service.

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93. If the inspections reveal any violations against the rights of the applicant, the officer(s) of Roszdravnadzor responsible are prosecuted in accordance with the legislation of the Russian Federation.

The procedure and frequency of the scheduled and unscheduled inspections  
of the efficiency and quality of how the State Service is provided,  
including the procedures and methods of controlling  
the efficiency and quality of the State Service

94. Monitoring the efficiency and quality of how the State Service is provided involves audits, identifying and eliminating any violations against the rights of an applicant, evaluations, decision-making, and preparing responses to the applicants who submitted complaints regarding the action or inaction of the officers of Roszdravnadzor responsible for providing the State Service.

95. Inspections are scheduled by the head of Roszdravnadzor.

96. The inspections can be scheduled (based on the annual work plan of Roszdravnadzor) or unscheduled.

97. Unscheduled inspections are performed when there is a specific request (complaint) by an individual or legal entity.

98. The results of the scheduled and unscheduled inspections highlight the identified issues and their suggested resolutions; the results are recorded as acts by Roszdravnadzor.

Responsibilities of the officials of the federal body  
of executive authority for their decisions and actions (or inactions)  
while providing the State Service

99. The responsibilities of the officers of Roszdravnadzor for providing the State Service are specified in the official regulations in accordance with the requirements of the legislation of the Russian Federation.

100. The officer responsible for performing the following administrative procedures of the Administrative Regulations is personally responsible for:

- 1) the results of processing the documents submitted by an applicant complying with the requirements of the legislation of the Russian Federation;
- 2) following the terms and regulations for receiving documents;
- 3) following the procedure for providing the State Service, including following the specified timeframe;
- 4) the accuracy of the information included in the state register of medical devices and the organizations engaged in the production and manufacture of medical devices.

Provisions describing the requirements for the procedure  
and control methods for providing the State Service,

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including provisions for individuals and their associations  
and organizations

101. Individuals and their associations and organizations can monitor the process of how the State Service is being provided by requesting information by phone, in writing, e-mail, or from the official Roszdravnadzor site and the Common Government Services Portal.

#### V. The Pre-judicial Procedure for Filing a Complaint Regarding Decisions and Actions (or Inactions) of Roszdravnadzor and Officials of Roszdravnadzor

Information about the rights of the applicant  
to a pre-judicial complaint against the decisions and actions (or inactions)  
of Roszdravnadzor while the State Service is being provided

102. The applicant has the right to a pre-judicial complaint against the decisions and actions (or inactions) of the officers of Roszdravnadzor while the State Service is being provided.

103. The applicant may file a complaint if an officer of Roszdravnadzor:

- misses the deadline for registering the application;
- misses the deadline for providing the State Service;
- requests documents from the applicant that are not specified in the normative legal acts of the Russian Federation for the State Service to be provided;
- refuses to accept documents submitted in accordance with the normative legal acts of the Russian Federation that are required for the State Service;
- refuses to provide the State Service on grounds that do not comply with the federal laws and/or are not in accordance with other normative legal acts of the Russian Federation;
- requests the applicant pay a state fee not stipulated by the normative legal acts of the Russian Federation;
- refuses to correct typos and/or errors found in the provided information.

#### Grounds for complaints

104. A violation of the rights and legitimate interests of the applicant, unlawful decisions, actions, or inactions of officials while providing the State Service, refusal to comply with the provisions of the Administrative Regulations, misconduct, or a violation of professional ethics while providing the State Service constitute grounds for a complaint.

State authorities and officials authorized to receive complaints

105. Complaints about unlawful decisions or actions (or inactions) by the officials providing the State Service are processed by Roszdravnadzor.

If the complaint is regarding a decision by a head official of Roszdravnadzor, the complaint is referred to a higher authority (the Ministry of Health of the Russian Federation).

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The procedure for filing a complaint and how a complaint is processed

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106. All complaints should be made to Roszdravnadzor in writing or electronically.

107. All complaints must contain the following:

- the name of the organization providing the State Service; the last name, first name, and patronymic of the official whose decisions or actions (or inactions) are the subject of the complaint;
- the last name, first name, patronymic, and the address of the applicant (if the applicant is an individual) or the name and address of the applicant (if the applicant is a legal entity); a phone number, an e-mail address (if available), and the mailing address where the response to the complaint should be sent;
- information about the decision or action (or inaction) of the Roszdravnadzor officials that are the subject of the complaint;
- the reason(s) why the applicant disagrees with the decision or action (or inaction) of the Roszdravnadzor official. The applicant may present the original documents (if available) or copies thereof as proof of the reasons of the complaint.

108. If the complaint is filed by a representative of the applicant, a document confirming the authority of the representative to act on behalf of the applicant must be submitted. The following documents may be used to confirm the authority of a representative to act on behalf of an applicant:

- a power of attorney (for individuals) executed in accordance with the legislation of the Russian Federation;
- a power of attorney (for legal entities) certified by the seal of the applicant and signed by the head of the legal entity or an individual authorized by the head of the legal entity in accordance with the legislation of the Russian Federation;
- a copy of the decision about the appointment or election of an individual or an order appointing the individual to a position that allows the individual to act on behalf of the applicant without a power of attorney.

109. The complaint may be submitted to Roszdravnadzor by mail, e-mail, through the official Roszdravnadzor site or through the Common Government Services Portal.

110. When filing a complaint in person, the applicant must provide an identification document in accordance with the legislation of the Russian Federation.

111. When filing a complaint electronically, the documents specified in [Section 108](#) of the Administrative Regulations should be signed with an electronic signature in accordance with the legislation of the Russian Federation; an identification document is not required.

112. The complaint is processed by the authorized officials.

113. The response with the results of processing the complaint contains the following:

- name of the organization providing the State Service; last name, first name, patronymic, and position of the official who made the decision regarding the complaint;
  - number, date, and location of where the decision was made;
  - information about the official whose decision or action (inaction) is the subject of the complaint;
  - last name, first name, and patronymic of the applicant or the name of the organization acting as an applicant;
  - grounds for the decision regarding the complaint;
  - the decision regarding the complaint;
  - if the complaint is justified, the deadlines for eliminating the issue(s), including the deadline for providing
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the State Service;  
information about how to appeal the decision regarding the complaint.

114. The response containing the results of processing the complaint is signed by the authorized official who processed the complaint.

115. If there are signs of an administrative offense or evidence of a crime while the complaint is being processed, the authorized official must submit all of the relevant materials to the prosecuting authorities.

#### Timeframe for processing a complaint

116. Complaints received by Roszdravnadzor must be registered within 1 business day.

117. Complaints received by Roszdravnadzor must be processed by authorized officials within 15 business days from the date the complaint is registered.

118. If the applicant files a complaint regarding a refusal by Roszdravnadzor to accept documents from the applicant or to correct typos and errors, the complaint is processed within 5 business days from the date the complaint is registered.

#### Grounds for suspending the processing of a complaint in accordance with the legislation of the Russian Federation

119. There are no grounds for suspending the processing of a complaint.

#### The results of processing a complaint

120. Roszdravnadzor decides what action to take in regards to the complaint based on the results of processing the complaint.

121. If the complaint is judged valid, Roszdravnadzor takes comprehensive measures to eliminate all violations and gives the results of the State Service to the applicant.

122. Roszdravnadzor refuses to take action regarding the complaint in the following cases:  
if there is a court decision that has been enforced regarding a complaint about the same subject and on the same grounds;  
the complaint is filed by an individual who is not authorized to file a complaint in accordance with the legislation of the Russian Federation;  
there is an earlier decision regarding a complaint on the same subject filed by the same individual made in accordance with the requirements for processing a complaint.

123. Roszdravnadzor has the right not to respond to the complaint in the following cases:  
the complaint contains obscene or abusive language; the life, health, and/or property of an official, including the official's family members, are threatened;

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if the text of the complaint is illegible, the complaint is not submitted for processing and an answer is not provided; however, if the name and address of the individual filing the complaint is legible, the individual is notified that the complaint could not be accepted;  
lack of information regarding: the subject of the complaint (including the decision, action, or inaction), the responsible officer, and/or the name and address (or e-mail address) of the applicant where a response should be sent.

The procedure for informing an individual who filed a complaint  
about the results of processing the complaint

124. The response with the results of processing the complaint is signed by an authorized official and is sent to the applicant (as specified by the applicant) by mail or electronically with the electronic signature of the official responsible for processing the complaint within 1 business day from the date the decision regarding the complaint is made. The form of the response is established by the legislation of the Russian Federation.

The applicant's right to obtain information and documents  
required for supporting a complaint and for the processing of a complaint

125. The applicant has the right to receive comprehensive information and all documents required for supporting a complaint and for the processing of a complaint.

Methods of informing the applicant about the procedure for filing a complaint  
and how a complaint is processed

126. Roszdravnadzor consults applicants by phone, e-mail, and/or in person about the procedure for filing a complaint regarding the decisions, actions, or inactions of Roszdravnadzor and its officials.



Attachment № 1  
 to the Administrative Regulations of  
 the Federal Service on Surveillance in Healthcare  
 for providing the state service of medical device registration  
 approved by Order № 737n of the Ministry of Health  
 of the Russian Federation dated October 14, 2013

Form

(to be printed on an organization's letterhead)

To: the Federal Service on  
 Surveillance in Healthcare  
 4 Slavyanskaya Ploshchad, Building 1  
 Moscow, 109074  
 p. 1

Application

- <\*> for the state registration of a medical device
- <\*> for amending the registration certificate of a medical device
- <\*> for replacing the registration certificate of a medical device

1.	Name of the medical device (including the accessories required for using the device as intended) <*>	
2.	Information regarding the developer of the medical device:	
2.1	Legal form and full name	
2.2	Abbreviated name (if available)	
2.3	Brand name (if available)	
2.4	Physical address	
2.5	Phone number(s)	
2.6	E-mail address (if available)	
2.7	Taxpayer Identification Number	
3.	Information regarding the manufacturer of a medical device:	
3.1	Legal form and full name	
3.2	Abbreviated name (if available)	
3.3	Brand name (if available)	
3.4	Physical address	
3.5	Phone number(s)	
3.6	E-mail address (if available)	

3.7	Taxpayer Identification Number	
4.	Information regarding the authorized representative of the manufacturer of the medical device:	
4.1	Legal form and full name	
4.2	Abbreviated name (if available)	
4.3	Brand name (if available)	
4.4	Physical address	
4.5	Phone number(s)	
4.6	E-mail address (if available)	
4.7	Taxpayer Identification Number	
5.	Information regarding the legal entity receiving the registration certificate:	
5.1	Legal form and full name	
5.2	Abbreviated name (if available)	
5.3	Brand name (if available)	
5.4	Physical address	
5.5	Phone number(s)	
5.6	E-mail address (if available)	
5.7	Taxpayer Identification Number	
6.	The production site of the medical device	
7.	Purpose of the medical device, stated by the manufacturer	
8.	Type of the medical device, in accordance with the nomenclature classification of medical devices	
9.	Class of the potential risk of the use of the medical device, in accordance with the nomenclature classification of medical devices	
10.	All-Russian Product Classification Code for the medical device	
11.	Method for obtaining information regarding the procedure for the state registration of a medical device	
12.	Method for receiving the registration certificate of a medical device	<*> Hard copy, in person <*> Hard copy, by registered mail with a return receipt <*> Electronically <*> Other
13.	Proof of payment of the state fee <***> (date and payment order number)	

-----  
<\*> Select one.

<\*> The list of the accessories required for using the medical device as intended  
can be submitted as an attachment certified with a seal and the signature of an authorized  
individual.

<\*\*\*> It is the applicant's responsibility to provide these documents.

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(Full name of the head of the legal entity or other individual  
authorized to act on behalf of this legal entity)

\_\_\_\_\_ 20\_\_  
(Date)

Seal

\_\_\_\_\_  
(Signature)

Attachment № 2  
to the Administrative Regulations of  
the Federal Service on Surveillance in Healthcare  
for providing the state service of medical device registration  
approved by Order № 737n of the Ministry of Health  
of the Russian Federation dated October 14, 2013

List of submitted documents

This certifies that \_\_\_\_\_  
(Name of the applicant)

submitted the following documents to the Federal Service on Surveillance in Healthcare  
for:

- <\*> the state registration of a medical device
- <\*> amending the state registration of a medical device

№	Document	Number of pages
1	Application	
2	Copy of the document confirming the authority of the representative of the manufacturer	
3	Information regarding the normative documents for the medical device	
4	Technical documentation for the medical device	
5	Operational documentation for the medical device, including the instruction manual	
6	Photographs with a general view of the medical device and any accessories required for using the medical device (at least 18 x 24 cm in size)	
7	Documents with the results of the technical tests of the medical device	
8	Documents with the results of the toxicological studies (for medical devices requiring contact with the human body)	
9	Documents with the results of the tests for approving the type of measuring instrument (for medical devices defined as measuring instruments by the state regulations for measurement uniformity)	
10	A copy of the proof of the payment of the state fee for the state registration of a medical device provided by an authorized federal executive authority <***>	
11	Power of Attorney	

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<\*> Select one.

<\*\*\*> It is the applicant's responsibility to provide these documents.

Documents submitted by  
the applicant:

\_\_\_\_\_  
(Full name, Position, Signature)

\_\_\_\_\_  
(Details of the Power of Attorney)

Documents received by the official  
of the registering authority:

\_\_\_\_\_  
(Full name, Position, Signature)

Date \_\_\_\_\_

Incoming N° \_\_\_\_\_

Number of pages \_\_\_\_\_

Seal

Attachment № 3  
 to the Administrative Regulations of  
 the Federal Service on Surveillance in Healthcare  
 for providing the state service of medical device registration  
 approved by Order № 737n of the Ministry of Health  
 of the Russian Federation dated October 14, 2013

Form

(to be printed on an organization's letterhead)

To: the Federal Service on  
 Surveillance in Healthcare  
 4 Slavyanskaya Ploshchad, Building 1  
 Moscow, 109074  
 p. 1

Application

<\*> for a duplicate registration certificate of a medical device

1.	Name of the medical device (including the accessories required for using the device as intended) <*>	
2.	Information regarding the developer of the medical device:	
2.1	Legal form and the full name	
2.2	Abbreviated name (if available)	
2.3	Brand name (if available)	
2.4	Physical address	
2.5	Phone number(s)	
2.6	E-mail address of the legal entity (if available)	
2.7	Taxpayer Identification Number	
3.	Information regarding the manufacturer of a medical device:	
3.1	Legal form and the full name of the legal entity	
3.2	Abbreviated name of the legal entity (if available)	
3.3	Brand name of the legal entity (if available)	
3.4	Physical address of the legal entity	
3.5	Phone number(s)	
3.6	E-mail address of the legal entity (if available)	
3.7	Taxpayer Identification Number	

4.	Information regarding the authorized representative of the manufacturer of the medical device:	
4.1	Legal form and the full name	
4.2	Abbreviated name (if available)	
4.3	Brand name (if available)	
4.4	Physical address	
4.5	Phone number(s)	
4.6	E-mail address (if available)	
4.7	Taxpayer Identification Number	
5.	Information regarding the legal entity receiving the registration certificate:	
5.1	Legal form and full name	
5.2	Abbreviated name (if available)	
5.3	Brand name (if available)	
5.4	Physical address	
5.5	Phone number(s)	
5.6	E-mail address (if available)	
5.7	Taxpayer Identification Number	
6.	The production site of the medical device	
7.	Purpose of the medical device, stated by the manufacturer	
8.	Type of the medical device, in accordance with the nomenclature classification of medical devices	
9.	Class of the potential risk of the use of the medical device, in accordance with the nomenclature classification of medical devices	
10.	All-Russian Product Classification Code for the medical device	
11.	Method for obtaining information regarding the procedure for the state registration of a medical device	
12.	Method for receiving the registration certificate of a medical device	<*> Hard copy, in person <*> Hard copy, by registered mail with a return receipt <*> Electronically <*> Other
13.	Reason for requesting a duplicate	
14.	Proof of payment of the state fee <***> (date and payment order number)	

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<\*> Select one.

<\*\*\*> The list of the accessories required for using the medical device as intended  
can be submitted as an attachment certified with a seal and the signature of an authorized  
individual.

<\*\*\*\*> It is the applicant's responsibility to provide these documents.

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(Full name of the head of the legal entity or other individual  
authorized to act on behalf of this legal entity)

\_\_\_\_\_ 20\_\_\_\_  
(Date)

Seal

\_\_\_\_\_  
(Signature)



Attachment № 4  
to the Administrative Regulations of  
the Federal Service on Surveillance in Healthcare  
for providing the state service of medical device registration  
approved by Order № 737n of the Ministry of Health  
of the Russian Federation dated October 14, 2013

Form

(to be printed on an organization's letterhead)

To: the Federal Service on  
Surveillance in Healthcare  
4 Slavyanskaya Ploshchad, Building 1  
Moscow, 109074  
p. 1

An application for resuming  
the state registration of a medical device

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(Name of the applicant (full name and abbreviated name (if available),  
brand name, legal form of the legal entity))

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is requesting for the state registration of the following medical device  
to be resumed:

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(Name of the medical device (including the accessories  
required for using the device as intended))

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(Registration file number)

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The results of the clinical tests of the medical device are attached.

Attachment: 1 copy (\_\_ pages)

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(Full name of the head of the legal entity or other individual  
authorized to act on behalf of this legal entity)

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\_\_\_\_\_ 20\_\_  
(Date)

Seal

\_\_\_\_\_  
(Signature)

Attachment № 5  
to the Administrative Regulations of  
the Federal Service on Surveillance in Healthcare  
for providing the state service of medical device registration  
approved by Order № 737n of the Ministry of Health  
of the Russian Federation dated October 14, 2013

Form

(to be printed on an organization's letterhead)

To: the Federal Service on  
Surveillance in Healthcare  
4 Slavyanskaya Ploshchad, Building 1  
Moscow, 109074  
p. 1

Application for cancelling the state registration of a medical device

\_\_\_\_\_  
(Name of the applicant (full name and abbreviated name (if available),  
brand name, legal form of the legal entity))

is requesting the cancellation of the state registration of the following medical device:

\_\_\_\_\_  
(Name of the medical device (including the accessories  
required for using the device as intended))

\_\_\_\_\_  
(Date of the state registration of the medical device and the registration number)

for the following reason: \_\_\_\_\_

(State the reason)

\_\_\_\_\_  
(Full name of the head of the legal entity or other individual  
authorized to act on behalf of this legal entity)

\_\_\_\_ 20 \_\_\_\_  
(Date)

Seal

\_\_\_\_\_  
(Signature)

Attachment № 6  
to the Administrative Regulations of  
the Federal Service on Surveillance in Healthcare  
for providing the state service of medical device registration  
approved by Order № 737n of the Ministry of Health  
of the Russian Federation dated October 14, 2013

DIAGRAM OF THE PROCEDURE FOR PROVIDING THE STATE SERVICE



