

GOVERNMENT OF THE RUSSIAN FEDERATION

ORDER

No. 804, dated June 02, 2020

MOSCOW

To amend specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device

The Government of the Russian Federation **has hereby ordered:**

1. To approve the submitted amendments introduced to specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device, approved by Order of the Government of the Russian Federation No. 430 dated April 03, 2020 “On certain specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device” (Official Internet Portal of Legal Information (www.pravo.gov.ru), 2020, 6 April, No. 0001202004060033).

2. This order comes into full force on the day of its official publication.

Chairman of the Government
of the Russian Federation

M. Mishustin

[SEAL: CENTRAL OFFICE OF THE GOVERNMENT OF THE RUSSIAN
FEDERATION*

RECORDS MANAGEMENT DEPARTMENT OF THE
GOVERNMENT OF THE RUSSIAN FEDERATION

No. 1]

APPROVED by Order of the
Government of the Russian
Federation of June 02, 2020, no. 804

A M E N D M E N T S

**introduced to the specific features of the circulation of medical devices,
including but not limited to the marketing authorisation of a batch (lot) of a
medical device**

1. Item 1: replace the word “Addendum” with the words “Addendum No. 1”.
2. Paragraph eight item 3: after the words “In the event of conducting”, add the words “in the Russian Federation”.

3. Item 4: supplement with the following paragraphs:

“In the event that it is insufficient for the expert institution to make a conclusion on the materials and information contained in the documents submitted by the Applicant, provided for by item 3 of this document, the expert institution shall send the Applicant within 2 business days a request for submission of the necessary information indicating the nature of the comments and how to eliminate the same (hereinafter referred to as the request) by recorded delivery or in the form of an electronic document signed by electronic signature or delivered via telecommunication channels.

The Applicant must submit a response to the request of the expert institution within a period not exceeding 5 business days from the date of receipt of the request. The expert institution shall prepare a report within 2 business days of receiving a response to the Applicant's request.

In the event of failure to submit a response to the request after 5 business days, the expert institution shall prepare a report on the basis of documents available.”

4. Sub-item “e” item 5: replace the word “Addendum” with the words “Addendum No. 1”.

5. First paragraph item 6: replace the number “3” with the number “2”.

6. Add items 7¹–7⁴ as follows:

“7¹. With regard to the medical devices specified in items 1-18 of Addendum No. 1 hereto, it is allowed to make changes to the name of the medical device in terms of changing information about its serial number (if any), batch (lot) number, in the event that other information contained in the documents of the registration dossier remained unchanged.

7². To amend documents in the registration dossier through changes specified in item 7¹ hereof, the Applicant shall submit (sends) to the Federal Service for Surveillance in Healthcare:

an application for amending the documents contained in the registration dossier (hereinafter the application for making amendments), carried out in accordance with paragraph 9 of the Registration Rules;

a copy of the document confirming the authority of the manufacturer's (producer's) authorised representative (if any);

documents confirming legal ownership by the Applicant of the batches (lots) of the medical device;

photographic images of the general configuration of the medical device together with the accessories needed for its intended application (in size at least 18 x 24 cm);

manufacturer's document confirming that the medical device with declared serial numbers (if any), batch (lot) numbers is identical to that initially registered in accordance with the said document;

a copy of the marketing authorisation certificate;

list of documents.

If the documents mentioned above are drawn up in a foreign language, they shall be presented with a duly certified translation into Russian.

7³. The Applicant shall submit to the Federal Service for Surveillance in Healthcare the application for amendments and documents referred to in item 7² hereof in hard copy by hand or send by recorded delivery with a list of enclosures, or as soft copy.

The Federal Service for Surveillance in Healthcare shall accept the application for amendments and documents referred to in item 7² hereof as per the checklist.

7⁴. The Federal Service for Surveillance in Healthcare shall check within 3 business days of receipt of the application for amendments and documents referred to in item 7² hereof the completeness and accuracy of information contained therein and:

a) makes a decision on amending the documents contained in the registration dossier, which is drawn up on the order of the Federal Service for Surveillance in Healthcare, entering the relevant information in the state register of medical devices and organizations (individual entrepreneurs) engaged in the production and manufacture of medical devices, or a decision to return the application for amendments and documents referred to in item 7² hereof, indicating the reasons for their return

b) a written notification sent to the Applicant on the decision made by recorded delivery enclosing the renewed registration certificate (in the event of making changes to it) and the previously issued registration certificate with an indication of its invalidity (indicating the date)."

7. Item 8:

a) supplement sub-item "a" with the words "as well as the application for amendments and documents referred to in item 7² hereof";

b) supplement sub-item "d" with the words "and copies of notifications drawn up by the Federal Service for Surveillance in Healthcare".

8. Item 10:

a) restate the first sentence in the first paragraph as follows:

"10. It is possible to import into the Russian Federation medical devices without authorisation issued by the Federal Service for Surveillance in Healthcare without registration, provided they are included in the list as per Addendum No. 1 to this document, in the amount necessary for any related tests (studies) or for the marketing authorisation process and further implementation."

b) second paragraph:

replace the words “It is possible to sell” with the words “It is possible to import into the Russian Federation, sell, transport, store, use and dispose (destroy)”;

replace the word “Addendum” with the words “Addendum No. 1”.

c) restate the third paragraph as follows:

“The Applicant must, within 3 business days from the date of importation of unregistered medical devices into the Russian Federation, send to the Federal Service for Surveillance in Healthcare an information on batches (lots) of medical devices in accordance with Addendum No. 2 hereto.”

d) reword the fifth paragraph as follows:

“The Applicant shall, on a weekly basis, until January 01, 2021, with regard to the unregistered and registered medical devices referred to in items 21-30 of Addendum No. 1 hereto in accordance with this document and with the marketing authorisation of medical devices rules, send to the Federal Service for Surveillance in Healthcare any information according to Addendum No. 2 hereto concerning implementation thereof, on their export from the territory of the Russian Federation or their destruction in accordance with this document.”

9. Reword the Addendum to these specific features as follows:

“ADDENDUM No. 1 to specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device, approved by Order of the Government of the Russian Federation No. 804 dated June 02, 2020.”

L I S T

of medical devices intended for use in the course of military conflicts, emergencies, emergency preventive actions, prevention and treatment of conditions representing a significant public threat, as well as conditions and damage resulting from the effect of unfavourable chemical, biological and radiological factors.

Type	Name of device
1. 169180	Immobile ventilator, high frequency, with electrical drive
2. 121270	Manual ventilation device, disposable
3. 121180	Manual ventilation device, reusable
4. 114040	Portable ventilator, with air drive
5. 113890	Portable ventilator, with electrical drive
6. 311390	Portable ventilator, with air drive, high frequency
7. 314540	Immobile ventilator, with air drive, high frequency
8. 314860	Emergency vehicle ventilator, with air drive, high frequency
9. 318710	CPAP mode ventilator, for home use
10. 326140	CPAP mode ventilator, for newborns
11. 287620	Negative pressure (suction) mode ventilator
12. 216540	Pneumatically driven automated ventilation device, reusable
13. 232870	ICU ventilator for newborn/adult patients
14. 232880	ICU ventilator for newborn patients
15. 232890	ICU ventilator, general purpose
16. 274590	Emergency vehicle ventilator, with electrical drive
17. 275750	A&R ventilator
18. 216260	Pneumatically driven automated ventilation device, disposable
19. 115610	Extracorporeal membrane oxygenator*

Type	Name of device
20. 131520	Intravascular membrane oxygenator*
21. 142010	Antigens for SARS coronavirus, IVD set, immunochromatographic assay, express test
22. 142100	Antibodies for SARS coronavirus, immunoglobulin class G (IgG)/AgM, IVD set, for ELISA
23. 142120	Antibodies for SARS coronavirus, immunoglobulin class G (IgG)/AgM, IVD set, for immunofluorescence assay
24. 142130	Antibodies for SARS coronavirus, immunoglobulin class M (IgM), IVD set, for ELISA test
25. 142150	Antibodies for SARS coronavirus, immunoglobulin class M (IgM), IVD set, for immunofluorescence assay
26. 142160	SARS coronavirus, nucleic acid, IVD set, for NA test
27. 142250	Antibodies for SARS coronavirus, immunoglobulin class A (IgA)/IgGAgM, IVD set, immunochromatographic assay, express test
28. 142260	Antibodies for SARS coronavirus, immunoglobulin class G (IgG), IVD set, for ELISA
29. 142280	Antigens for SARS coronavirus, IVD set, for enzyme-linked immunosorbent assay (ELISA)
30. 142300	Antibodies for SARS coronavirus, immunoglobulin class G (IgG), IVD set, for immunofluorescence assay
31. 343600	Reusable eye protective screen
32. 142020	Antibodies for SARS coronavirus, immunoglobulin class A (IgA)/IgGAgM IVD set, control material
33. 142030	Antibodies for SARS coronavirus, immunoglobulin class G (IgG) IVD set, calibrator
34. 142050	Antigens for SARS coronavirus, IVD set, calibrator
35. 142060	Antibodies for SARS coronavirus, immunoglobulin class A (IgA)/IgGAgM IVD set, reagent
36. 142070	Antibodies for SARS coronavirus, immunoglobulin class G (IgG) IVD set, control material
37. 142080	Antigens for SARS coronavirus, IVD set, control material
38. 142090	Antibodies for SARS coronavirus, immunoglobulin class G (IgG) IVD set, reagent
39. 142110	Antigens for SARS coronavirus, IVD set, reagent
40. 142140	Antibodies for SARS coronavirus, immunoglobulin class G (IgG)/IgM IVD set, calibrator
41. 142170	Antibodies for SARS coronavirus, immunoglobulin class G (IgG)AgM IVD set, control material
42. 142180	Antibodies for SARS coronavirus, immunoglobulin class M (IgM) IVD set, calibrator

Type	Name of device
43. 142190	SARS coronavirus, nucleic acid, IVD set, calibrator
44. 142200	Antibodies for SARS coronavirus, immunoglobulin class G (IgG)/IgM IVD set, reagent
45. 142210	Antibodies for SARS coronavirus, immunoglobulin class M (IgM) IVD set, control material
46. 142220	SARS coronavirus, nucleic acid, IVD set, control material
47. 142230	Antibodies for SARS coronavirus, immunoglobulin class M (IgM) IVD set, reagent
48. 142240	SARS coronavirus, nucleic acid, IVD set, reagent
49. 142290	Antibodies for SARS coronavirus, immunoglobulin class A (IgA)/IgG/IgM, IVD set, calibrator
50. 152850	IVD set for extraction\isolation of nucleic acids
51. 349480	Non-specific set for biomaterial sampling (sampling, pre-treatment and transportation)
52. 191780	Artificial blood circulation (ABC) system, non-rolling pump type
53. 191810	Artificial blood circulation (ABC) system, rolling pump type
54. 209090	Extracorporeal oxygenation/ventilation system, portable
55. 104010	Isolating overall
56. 122540	Gloves for manual examination/interventions, made of natural hevea latex, non-powdered, non-sterile
57. 122560	Gloves for manual examination/interventions, made of natural hevea latex, powdered
58. 129350	Surgical gown, disposable*
59. 129380	Surgical gown, reusable
60. 129870	Isolating gown, reusable
61. 129880	Isolating gown, disposable*
62. 132380	Facial mask for respiratory protection, reusable
63. 139350	Gloves for manual examination/interventions, made of polychloroprene, non-powdered
64. 139360	Gloves for manual examination/interventions, made of polychloroprene, powdered
65. 141650	Overshoes non-conductive, non-sterile*
66. 157010	Patient's gown, disposable*
67. 157240	Patient's gown, reusable
68. 164050	Gown for interventions, disposable
69. 164070	Gown for interventions, reusable
70. 180770	Breathing mask, general purpose*
71. 181360	Surgical isolating overall
72. 181520	Surgical mask, reusable

Type	Name of device
73. 181830	Surgical breathing mask
74. 182450	Surgical mask, disposable*
75. 185830	Gloves for manual examination/interventions, made of nitrile rubber, non-powdered, non-sterile
76. 185850	Gloves for manual examination/interventions, made of nitrile rubber, powdered
77. 188380	Surgical overall, cuffed*
78. 205280	Gloves for manual examination/interventions, made of vinyl, non-powdered
79. 205290	Gloves for manual examination/interventions, made of vinyl, powdered
80. 248320	Surgical overall, disposable, non-sterile
81. 269290	Overshoes, watertight
82. 293810	Overshoes, conductive, non-sterile*
83. 298450	Gloves for manual examination/interventions, made of guayule latex, non-powdered
84. 311720	Gloves for manual examination/interventions, made of ethylene vinyl acetate, non-powdered, non-sterile
85. 320790	Gloves for manual examination/interventions, made of nitrile rubber, non-powdered, with anti-bacterial properties
86. 321530	Gloves for manual examination/interventions, made of polyisoprene, non-powdered
87. 332470	Set of overalls for surgery/examination
88. 349230	Gloves for manual examination/interventions, made of polyisoprene, powdered
89. 351490	Gloves for manual examination/interventions, made of natural hevea latex, non-powdered, non-sterile, with anti-bacterial properties
90. 367580	Facial mask for respiratory protection, disposable*
91. 126370	Infra-red thermometer for body temperature measurement, aural
92. 126390	Infra-red thermometer for body temperature measurement, skin-touch type
93. 184110	Medical thermometer with LCD display, disposable
94. 190030	Electronic thermometer (AC mains power required) for continuous temperature measurement
95. 190040	Electronic thermometer (battery power required) for continuous temperature measurement
96. 213720	Thermometer for body temperature measurement, capillary type, alcohol filled

Type	Name of device
97. 213740	Infra-red thermometer for body temperature measurement, capillary type, mercury filled
98. 254890	Optical fiber-based thermometer with temperature probe
99. 266210	Thermometer for body temperature measurement, electronic, for intermittent measurement mode
100. 300390	Thermometer for body temperature measurement, with colour coded temperature indication
101. 335240	Thermometer for body temperature measurement, capillary type, Gallium alloy filled
102. 339240	Medical thermometer with LCD display, reusable
103. 341680	Patient thermometer wireless, reusable
104. 341690	Patient thermometer wireless, disposable
105. 358080	Infra-red thermometer for body temperature measurement, skin-touch/aural type
106. 108170	Outpatient registration device for body temperature monitoring
107. 292390	Electronic micropipette
108. 216020	IVD semi-automatic thermocyclic nucleic acid thermocycler of laboratory grade
109. 215980	IVD automatic thermocyclic nucleic acid thermocycler of laboratory grade
110. 347450	IVD thermocyclic nucleic acid thermocycler for use near patient
111. 216000	IVD manual thermocyclic nucleic acid thermocycler
112. 318650	Automatic magnetic IVD particle separation device
113. 228180	Exchange window
114. 318660	Automatic device for preparation of IVD nucleic acids samples
115. 207000	IVD virus transport medium
116. 340600	Disposable container for IVD analysis
117. 259780	Non-specialized IVD sample collection sterile container with no additives
118. 108750	General-purpose sterile laboratory container
119. 259720	Non-specialized, non-sterile IVD sampling container with no additives
120. 293350	IVD vacuum collection tube for blood samples with dextrose B citrate (ACD-B)
121. 293360	IVD vacuum collection tube for blood samples with K3EDTA and sodium fluoride
122. 293370	IVD vacuum collection tube for blood samples with no additives
123. 293400	IVD vacuum collection tube for blood samples with potassium oxalate and sodium fluoride
124. 293420	IVD vacuum collection tube for blood samples with sodium heparin

Type	Name of device
125. 293440	IVD vacuum collection tube for blood samples with dextrose A citrate (ACD-A)
126. 293450	IVD vacuum collection tube for blood samples with ammonium heparin and separation gel
127. 293460	IVD vacuum collection tube for blood samples with lithium heparin and lithium iodoacetate
128. 293470	IVD vacuum collection tube for blood samples with CPhDA*
129. 293480	IVD vacuum collection tube for blood samples with lithium heparin and separation gel
130. 293500	IVD vacuum collection tube for blood samples with K2EDTA*
131. 293550	Vacuum container for IVD saliva samples with sodium azide
132. 264440	IVD centrifugal sterile tube
133. 134590	Cryobiological container
134. 167480	IVD non-vacuum collection tube for blood samples with no impurities,
135. 259790	IVD non-specialized tissue collection container with formalin solution
136. 264460	IVD centrifugal non-sterile tube
137. 167550	IVD non-vacuum collection tube for blood samples with sodium citrate
138. 167430	IVD non-vacuum collection tube for blood samples with EDTA*
139. 167440	IVD non-vacuum collection tube for blood samples with separation gel
140. 108710	General-purpose reusable laboratory container
141. 293660	IVD vacuum collection tube for blood samples with K3EDTA*
142. 293570	IVD vacuum collection tube for blood samples with coagulation activator
143. 167450	IVD non-vacuum collection tube for blood samples with lithium heparin
144. 293760	IVD vacuum collection tube for blood samples with lithium heparin
145. 293540	IVD vacuum collection tube for blood samples with sodium citrate
146. 343590	Reusable facial protective screen
147. 107700	Facial protective screen*
148. 274530	Eye protective screen*
149. 127430	Ultrasonic respiratory air/gas humidifier
150. 152090	Humidifier for respiratory mixtures with a heating element
151. 173070	Humidifier for respiratory mixtures without a heating element
152. 318730	Non-sterile disposable bacterial filter for medical gases
153. 324930	Non-sterile reusable bacterial filter for medical gases
154. 165140	Disposable connector for respiratory circuits

Type	Name of device
155. 165230	Reusable connector for respiratory circuits
156. 185620	Disposable moisture collector for artificial lung ventilation devices
157. 185630	Reusable moisture collector for artificial lung ventilation devices
158. 109720	Reusable facial mask of the continuous/two-phase positive airway pressure device,
159. 109740	Oral mask for artificial ventilation with continuous/two-phase positive pressure
160. 109710	Disposable facial mask of the continuous/two-phase positive airway pressure device,
161. 271370	Reusable mask for artificial lung ventilation
162. 271390	Disposable mask for artificial lung ventilation
163. 110230	Reusable tube/mask connector for respiratory circuits
164. 136690	Connector with plug for quick connection of medical air cylinders
165. 136820	Connector for quick connection of medical air cylinders with f-port
166. 151440	Reusable Y-shaped connector for respiratory circuits
167. 298870	Connector for quick connection in the helium-oxygen mixture supply system with f-port
168. 298880	Connector for quick connection in the helium-oxygen mixture supply system, with m-port
169. 275840	Connector for quick connection in the exhaust system of anaesthetic gases with m-port
170. 250830	Connector for NOS quick connection with f-port
171. 250770	Connector for NOS quick connection with m-port
172. 250740	Connector for hyponitrous oxide quick connection with f-port
173. 250710	Connector for hyponitrous oxide quick connection with m-port
174. 283370	Disposable bag for respiratory circuits
175. 283460	Reusable bag for respiratory circuits
176. 283480	Reusable gas flow sensor for breathing system
177. 105850	Nasal cannula for oxygen supply during mechanical ventilation with continuous positive pressure
178. 136410	Standard nasal cannula for oxygen supply*
179. 185520	Respiratory tube holder
180. 139780	Reusable spacer for nebulizer or inhaler
181. 345540	Disposable spacer for nebulizer or inhaler
182. 298900	Helium and oxygen mixer for breathing mixture
183. 344690	Oxygen/air gas mixer for emergency aid
184. 132340	Respiratory airway cleaning/suction tube for emergencies
185. 135720	Endobronchial tube
186. 136260	Disposable standard endotracheal tube

Type	Name of device
187. 136270	Reusable standard endotracheal tube
188. 136490	Reusable standard tracheostomy tube
189. 136500	Disposable standard tracheostomy tube
190. 136850	Medical air low-pressure tube
191. 169050	Reusable reinforced endotracheal tube
192. 169080	Disposable reinforced tracheostomy tube
193. 169100	Disposable reinforced endotracheal tube
194. 183640	Coaxial tube for hyponitrous oxide cylinder*
195. 191040	Disposable suction/flushing tube
196. 218780	Endotracheal antibacterial tube*
197. 250810	Low-pressure tube for hyponitrous oxide
198. 269300	Laser-resistant endotracheal tube
199. 271240	Disposable respiratory tube for gas collection/monitoring
200. 274010	Aerosol supply tube*
201. 275760	Tube for evacuating waste anaesthetic gases
202. 279070	Endotracheal tube with suction cup
203. 283260	Breathing system tube
204. 298800	Disposable vacuum tube
205. 298830	Reusable vacuum tube
206. 301700	Endotracheal tube for high-frequency mechanical ventilation
207. 332650	Disposable sterile respiratory tube for gas collection/monitoring
208. 332660	Reusable respiratory tube for gas collection/monitoring
209. 333030	Tube for monitoring pressure to the artificial blood circulation (ABC) system
210. 333510	Reusable respiratory tube for inspiratory/expiratory tube
211. 334110	Spirometry tube/lung function assessment
212. 348290	Duct cuff inflation tube
213. 349970	Customized tracheostomy tube
214. 351410	Reusable low-pressure gas tube for general use
215. 354450	Disposable non-sterile tube for inspiratory/expiratory extension
216. 357210	Reusable reinforced tracheostomy tube
217. 360480	Disposable sterile tube for inspiratory/expiratory extension
218. 207560	Reusable adapter for inhalation therapy
219. 110260	Replaceable filter for heat/moisture exchanger
220. 173800	Protective filter for tracheostomy*
221. 181090	Surgical instrument compressed air filter
222. 218750	Non-sterile heat/moisture exchanger/bacterial filter
223. 172720	Reusable oropharyngeal airway

Type	Name of device
224. 172730	Disposable oropharyngeal airway
225. 254040	Disposable tracheal airway with oesophageal obturator
226. 254120	Reusable oesophageal airway
227. 254170	Disposable airway with oesophageal obturator
228. 254240	Reusable tracheal airway with oesophageal obturator
229. 254280	Reusable nasopharyngeal airway
230. 254300	Disposable nasopharyngeal airway
231. 289900	Reusable stylet for airway
232. 290000	Disposable stylet for airway*
233. 318100	Device for pumping air out of a cuff for a laryngeal airway
234. 318110	Introducer for laryngeal airway
235. 283330	Disposable mouthpiece for respiratory circuits
236. 283380	Reusable mouthpiece for respiratory circuits
237. 325840	Filter/mouthpiece for checking lung function*
238. 350590	Valsalva's manoeuvre standard mouthpiece*
239. 351540	Cardiopulmonary resuscitation mouthpiece/cover
240. 364520	Valsalva's manoeuvre manometric mouthpiece
241. 172910	Tracheal tube cuff*
242. 172970	Tracheal tube cuff expander
243. 173780	Tracheostomy tube cuff
244. 289870	Pump for manual injection of air into the cuff of the endotracheal tube
245. 289980	Endotracheal tube cuff pressure monitor
246. 289880	Reusable endotracheal tube introducer
247. 289990	Disposable endotracheal tube introducer
248. 172930	Vacuum regulator in aspiration system for trachea
249. 108960	Disposable end-expiratory positive pressure valve
250. 109060	Reusable end-expiratory positive pressure valve
251. 124510	Disposable mechanical expiratory valve
252. 124630	Reusable mechanical expiratory valve
253. 135690	Endobronchial valve
254. 135700	Endobronchial valve catheter*
255. 135710	Endobronchial valve sizing kit
256. 168130	Reusable embedded check valve
257. 168140	Disposable embedded check valve
258. 236910	Exhalation valve with RF sensor*
259. 249420	Haemostatic valve obturator*
260. 260200	Connector for needleless connection with direct-flow valve

Type	Name of device
261. 262380	Reusable non-reversible valve
262. 321960	Disposable non-reversible valve
263. 337110	Resistance valve for cardiopulmonary resuscitation, for inhalation/exhalation
264. 327780	Medical gas flowmeter with Thorpe tube
265. 151450	Disposable Y-shaped connector for respiratory circuits
266. 182020	Surgical instrument compressed air quick connector with f-port
267. 182030	Surgical instrument compressed air quick connector with m-port
268. 256770	Reusable low-pressure tube connector
269. 275690	Connector for quick connection in the exhaust system of anaesthetic gases with f-port
270. 298760	Vacuum quick connector with f-port
271. 298770	Vacuum quick connector with m-port
272. 327610	Disposable non-sterile tube/mask connector for respiratory circuits
273. 327640	Disposable sterile tube/mask connector for respiratory circuits
274. 115570	Extracorporeal vesiculate oxygenator*
275. 191500	Air bubble/fluid level detector for the artificial blood circulation (ABC) system
276. 191740	The air/foam detector for the artificial blood circulation (ABC) system
277. 191920	Cardiotomy reservoir*
278. 191770	Centrifugal pump for the artificial blood circulation (ABC) system
279. 264520	Centrifugal pump for the artificial blood circulation (ABC) system with power supply
280. 115660	Device for extracorporeal monitoring of blood gases/pH
281. 191440	Cardioplegic solution adapter*
282. 191560	Set of tubes for the artificial blood circulation (ABC) system
283. 327170	General-purpose laboratory research tablet
284. 327110	IVD microplate*
285. 209360	Mobile unit for creating a laminar flow
286. 182750	Surgical unit for creating a laminar flow
287. 152700	Highly efficient stationary air filter
288. 152690	Mobile highly effective air filtering purifier
289. 131980	UV bactericidal lamp
290. 347590	UV light disinfection system
291. 157200	Pulse oximetry patient monitoring system module
292. 150020	Pulse oximeter with power supply
293. 149980	Battery powered pulse oximeter
294. 218410	Telemetry pulse oximeter

Type	Name of device
295. 220960	Thermographic camera
296. 126320	Infrared Thermographic System
297. 157680	Medical bedside console with communications
298. 259390	Universal console with communications
299. 259380	Universal console with communication leads and ceiling mount
300. 188360	High-flow infusion pump with the ability to heat the injected media
301. 288180	Elastomeric infusion pump*
302. 124530	Reusable mechanical general-purpose infusion pump
303. 183030	Multi-channel general-purpose infusion pump
304. 260420	General-purpose infusion pump with power supply
305. 329460	Battery-powered general-purpose infusion pump
306. 333950	Disposable mechanical general-purpose infusion pump
307. 324350	Disposable flexible, single-use video bronchoscope
308. 179300	Reusable flexible, single-use video bronchoscope
309. 143930	Hard bronchoscope
310. 179100	Flexible optical fiber bronchoscope
311. 182740	Surgical system for suction/irrigation
312. 358710	General-purpose electric aspiration surgical system
313. 358690	General-purpose pneumatic aspiration surgical system
314. 228190	Laminar air tent
315. 157130	Multifunctional patient monitoring system module
316. 190840	System for monitoring physiological parameters of several patients
317. 190850	System for monitoring physiological parameters of individual patient
318. 143910	Blood refrigerator
319. 215850	Pharmaceutical refrigerator
320. 261620	Basic laboratory refrigerator
321. 321680	Blood refrigerator/freezer
322. 352570	Laboratory refrigerator/freezer
323. 352580	Pharmacy refrigerator/freezer
324. 120210	Mechanical hospital bed
325. 136210	Standard hospital bed with electrical drive
326. 131200	Hospital bed with hydraulic drive
327. 248410	Microsample centrifuge
328. 214590	Cytological centrifuge
329. 117910	High speed floor-mounted centrifuge
330. 143900	Blood bank centrifuge
331. 260430	General-purpose centrifuge

Type	Name of device
332. 274470	Floor-mounted low speed centrifuge without cooling
333. 274480	Floor-mounted low speed centrifuge with cooling
334. 261720	Laboratory thermostat
335. 260440	General-purpose thermostat
336. 232840	Laboratory thermostat for clean rooms
337. 261300	Laboratory water bath with shaking action
338. 335060	Laboratory thermostatic stirrer
339. 327810	Medical gas flowmeter, with dial
340. 327750	Medical gas flowmeter with Bourdon tube pressure gauge
341. 156250	Respiratory oxygen therapy system
342. 191160	Stationary oxygen concentrator
343. 113810	Portable oxygen concentrator
344. 292810	Pipette tip*
345. 352690	IVD pipette tip*
346. 327180	IVD microplate-film*
347. 335550	Tray for multi-channel dispensers
348. 293530	IVD vacuum collection tube for blood samples with no additives/metal impurities
349. 272240	Antiseptic cloth*
350. 261820	Disposable general-purpose applicator/swab with absorbent tip, single use
351. 186000	IVD automatic immunochemiluminescent analyzer
352. 109770	Detergent/cleaning IVD-solution for automated/semi-automated systems
353. 160170	Buffer wash solution for automatic immunochemiluminescent analyzers
354. 231970	Substrate solution for automatic immunochemiluminescent analyzers
355. 231790	IVD flushing solution/flushing buffer for immunochemistry
356. 324430	Disposable reaction cuvettes/cuvettes for IVD laboratory analyser
357. 324440	Reusable reaction cuvettes/cuvettes for IVD laboratory analyser
358. 216350	Stationary electronic blood pressure monitor with automatic air inflation
359. 216560	Electronic monitor, automatic, portable, with finger cuff blood pressure
360. 216630	Electronic monitor, automatic, portable, with shoulder/wrist cuff blood pressure
361. 218430	Telemetry blood pressure meter
362. 206980	Kit for collecting and transporting samples with viruses

Type	Name of device
363. 347240	Oral oropharyngeal specimen collection kit

*Disposable medical devices.

10. Supplement with Addendum No. 2 as follows:

“ADDENDUM No. 2 to the specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device”

I N F O R M A T I O N

on medical devices submitted to the Federal Service for Surveillance in Healthcare

1. Name of the medical device (for registered medical devices, in accordance with the marketing authorisation).
2. Number and date of marketing authorisation for the medical device (for registered medical devices).
3. Hardware version or model of the medical device (if available).
4. Type code and name of the type of medical device in accordance with the nomenclature classification of medical devices by type approved by the Ministry of Healthcare of the Russian Federation.
5. Name of the medical device manufacturer (for registered medical devices, in accordance with marketing authorisation).
6. Name of the country of the medical device manufacturer (for registered medical devices, in accordance with marketing authorisation).
7. Address of the medical device production site (for registered medical devices, in accordance with marketing authorisation).
8. Composition and assembly units of the medical device (if available) and the list of accessories (if available) (for registered medical devices, in accordance with marketing authorisation).
9. Batch (lot) number, serial number.
10. Size of batch (lot) or the number of serial numbers, itemised.

11. Date of manufacture (production) of the medical device.

12. Expiry date of the medical device.

13. Information on the Applicant specified in item 3 of the specific features of the circulation of medical devices, including the state registration of a batch (lot) of medical devices, approved by Order of the Government of the Russian Federation No. 430 dated April 03, 2020 “On certain specific features of the circulation of medical devices, including but not limited to the marketing authorisation of a batch (lot) of a medical device” (full and abbreviated (if any) name, including the company name, legal form of the legal entity, its address, taxpayer identification number, main state registration number or surname, name and patronymic (if any), address of the place of residence of the individual entrepreneur, data on the identity document, main state registration number of the individual entrepreneur, phone number and email address).

14. Information about the person who stores the batch (lot), serial number of the medical device (full and abbreviated (if any) name, including the company name, legal form of the legal entity, its address, tax identification number, main state registration number or surname, name, patronymic (if any) of the individual entrepreneur, address of residence, data on the identity document, main state registration number of the individual entrepreneur, phone number and email address).

Information about the person to whom the batch (lot) was sold, serial numbers of the medical device (full and abbreviated (if any) name, including company name), legal form of the legal entity, its address, tax identification number, main state registration number or surname, name, patronymic (if any) of the individual entrepreneur, address of residence, data on the identity document, main state registration number of the individual entrepreneur, phone number and email address
