

FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE

**CERTIFICATE OF VALIDATION
FOR THE MEDICAL DEVICE
No P3H 2016/4191 of June 3, 2016**

For the medical device

The device for a rapid preparation of sterile washing solutions and feeding them to a surgical area "Geyser" according to the technical conditions No 9444-002-41031644-2015 with accessories

The certificate of validation is issued

Limited Liability company Production and Commercial Firm "Quartz" (LLC PCF "Quartz"), Russia, 660037, Krasnoyarsk city, 47A avenue n.a. gazety Krasnoyarsky Rabochy, bdlg. 48

Producer

Limited Liability company Production and Commercial Firm "Quartz" (LLC PCF "Quartz"), Russia, 660037, Krasnoyarsk city, 47A avenue n.a. gazety Krasnoyarsky Rabochy, bdlg. 48

Manufacturing place of the medical device

660004, Krasnoyarsk city, 2 Festivalnaya str., bldg. 145-150

Registration dossier number

ПД-8579/42186 dd. 17/09/2015

Medical device type

182740

Potential risk category of medical device appliance

2a

All-Russian Product Classifier Code for the medical device

94 4470

The certificate of validation contains supplement on 3 sheets

by the Order of the Federal Service for Surveillance in Healthcare No 4927 of June 3, 2016
admitted to applying in the territory of the Russian Federation

Head of the Federal Service

for Surveillance in Healthcare

/signature/

M.A. Murashko

Seal: /Ministry of Health of the Russian Federation*Federal Service for Surveillance in Healthcare/

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for use

**SUPPLEMENT TO CERTIFICATE OF VALIDATION
FOR THE MEDICAL DEVICE
No P3H 2016/4191 of June 3, 2016**

Sheet No 1

For the medical device

The device for a rapid preparation of sterile washing solutions and feeding them to a surgical area "Geyser" according to the technical conditions No 9444-002-41031644-2015 with accessories

Design variants:

I. The device for a rapid preparation of sterile washing solutions and feeding them to a surgical area "Geyser", variant 1, with accessories:

1. Set of change parts:

- 1.1. Irrigoaspirator for abdominal cavity – 1 pc.
- 1.2. Irrigoaspirator for pleural cavity – 1 pc.
- 1.3. Bent spray tube – 1 pc.
- 1.4. Straight spray tube – 1 pc.
- 1.5. Device for an approximation of wound edges – 1 pc.
- 1.6. Device for an intraoperative sanitation of the colon – 1 pc.
- 1.7. Adaptor for using irrigoaspirators with a laparoscope – 1 pc.

2. Set of installation elements:

- 2.1. Pipeline – 1 pc.
- 2.2. Water feed pipeline – 1 pc.
- 2.3. Water discharge pipeline – 1 pc.

3. Set of instruments:

- 3.1. Funnel – 1 pc.
- 3.2. Liquid level gage – 1 pc.
- 3.3. Primary filter – 1 pc.

Exploitation documentation:

1. Passport – 1 pc.
2. Operations manual – 1 pc.
3. Guidelines "Sanitation of abdominal cavity at diffuse purulent peritonitis using hyperosmolar solutions made with the "Geyser" – 1 pc.

II. The device for a rapid preparation of sterile washing solutions and feeding them to a surgical area "Geyser", variant 2, with accessories:

1. Set of change parts:

- 1.1. Irrigoaspirator for abdominal cavity – 1 pc.
- 1.2. Irrigoaspirator for pleural cavity – 1 pc.
- 1.3. Bent spray tube – 1 pc.
- 1.4. Straight spray tube – 1 pc.
- 1.5. Device for an approximation of wound edges – 1 pc.

Head of the Federal Service
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Sheet No 2

- 1.6. Device for an intraoperative sanitation of the colon – 1 pc.
- 1.7. Adaptor for using irrigoaspirators with a laparoscope – 1 pc.
2. Set of installation elements:
 - 2.1. Pipeline – 1 pc.
 - 2.2. Water feed pipeline – 1 pc.
 - 2.3. Water discharge pipeline – 1 pc.
 - 2.4. Foot switch – 1 pc.
3. Set of instruments:
 - 3.1. Funnel – 1 pc.
 - 3.2. Primary filter – 1 pc.
- Exploitation documentation:
 1. Passport – 1 pc.
 2. Operations manual – 1 pc.
 3. Guidelines “Sanitation of abdominal cavity at diffuse purulent peritonitis using hyperosmolar solutions made with the “Geyser” – 1 pc.
- III. The device for a rapid preparation of sterile washing solutions and feeding them to a surgical area “Geyser”, variant 3, with accessories:
 1. Set of change parts:
 - 1.1. Irrigoaspirator for abdominal cavity – 1 pc.
 - 1.2. Irrigoaspirator for pleural cavity – 1 pc.
 - 1.3. Bent spray tube – 1 pc.
 - 1.4. Straight spray tube – 1 pc.
 - 1.5. Device for an approximation of wound edges – 1 pc.
 - 1.6. Device for an intraoperative sanitation of the colon – 1 pc.
 - 1.7. Adaptor for using irrigoaspirators with a laparoscope – 1 pc.
 2. Set of installation elements:
 - 2.1. Pipeline – 1 pc.
 - 2.2. Water feed pipeline – 1 pc.
 - 2.3. Water discharge pipeline – 1 pc.
 - 2.4. Foot switch – 1 pc.
 3. Set of instruments:
 - 3.1. Funnel – 1 pc.
 - 3.2. Primary filter – 1 pc.
 - Exploitation documentation:
 1. Passport – 1 pc.

Head of the Federal Service
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**SUPPLEMENT TO CERTIFICATE OF VALIDATION
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Sheet No 3

2. Operations manual – 1 pc.
3. Guidelines “Sanitation of abdominal cavity at diffuse purulent peritonitis using hyperosmolar solutions made with the “Geyser” – 1 pc.

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Перевод с русского языка на английский язык выполнила переводчик: Кочетова Ксения Владимировна.

Translation from Russian into English is made by a translator Kochetova Ksenia Vladimirovna.

Кочетова Ксения Владимировна



СМ. НА ОБОРОТЕ

Город Краснодар, Краснодарский край, Российская Федерация.
Одиннадцатого июля две тысячи шестнадцатого года.

Я, Манько Татьяна Николаевна, нотариус Краснодарского нотариального округа, свидетельствую подлинность подписи, сделанной переводчиком Кочетовой Ксенией Владимировной в моем присутствии. Личность ее установлена.

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