

Specificație Completată		
Dispozitivul Medical	Tonometru portativ ocular	
Modelul	Diaton ТГ/Дл - 03	
Țara de origine	Rusia	
Producătorul	АО «ГПИЗ»	
Tonometru ocular portativ		
Cod	170300	
Descriere	Tonometrul ocular este destinat pentru masurarea presiunii intraoculare	
Parametru	Specificația	Specificație completată
Tip	non-corneal	DA non-corneal
Autocalibrare	da	DA
Precizie	≤20mmHg +/-2mm ≥20mmHg- +/-10%	DA
Ecran	LCD	LCD
Alimentare	baterii	DA bateriei - durata de lucru pîna la 5000 de investigații

Техническое задание на тонометр внутриглазного давления через веко цифровой портативный ТГДц-03

1. Тонометр внутриглазного давления через веко цифровой портативный ТГДц-03 предназначен для измерения тонометрического по Маклакову внутриглазного давления (ВГД) у детей и взрослых без применения анестезии.
2. Диапазон измерения тонометрического ВГД по Маклакову составляет от 5 до 63 мм рт. ст. Предел допускаемой погрешности измерения составляет ± 2 мм рт.ст. при измерениях в диапазоне от 5 до 26 мм рт.ст. включительно и $\pm 10\%$ - выше 26 мм рт.ст.
3. Проверка работоспособности тонометра производится на задатчике давления, входящем в комплект тонометра, при этом на дисплее отображается значение тестовой величины (26 ± 2) мм рт.ст.
4. По электробезопасности тонометр соответствует требованиям ГОСТ Р МЭК 60601-1-2010 и выполнен по степени защиты изделия типа В с внутренним источником питания.
5. Электропитание от двух элементов питания общим напряжением 3 В. Снижение напряжения электропитания до 2,55 В и ниже индицируется в виде символа "U".
6. Ток потребления не более 2 мА.
7. Средний срок службы не менее 5 лет.
8. Габаритные размеры тонометра (без футляра и задатчика давления) не более 176 x 26 x 20 мм.
9. Масса тонометра с элементами питания не более 105 г., без элементов питания не более 65 г. (без футляра и задатчика давления).
10. Тонометр обеспечивает 5000 циклов измерения без замены элементов питания.
11. Гарантийное срок эксплуатации тонометра 12 месяцев со дня продажи, если иное не указано в договоре (контракте).

Комплектность поставки тонометра

Наименование	Количество, шт.
Тонометр внутриглазного давления через веко цифровой портативный ТГДц-03	1
Устройство контроля работоспособности / задатчик давления	1
Футляр	1
Элемент электропитания VARTA AAA 1,5 V	2
Руководство по эксплуатации Часть I	1
Руководство по эксплуатации Часть 2	1
Памятка по обращению	1
Упаковка	I

Тонометр в футляре упаковывается в соответствии с требованиями ГОСТ Р 50444-92 и комплекта конструкторской документации предприятия-изготовителя в транспортную тару, в которую вкладывается упаковочный лист.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Holds Certificate Number:

MD 577118

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture, installation, distribution and servicing of active medical devices for ophthalmology, magnetic field therapy and sterilizers.

Производство, инсталляция, продажа и сервисное обслуживание активных медицинских изделий для офтальмологии, магнитной терапии и стерилизаторов.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-23

Latest Revision Date: 2020-01-24

Effective Date: 2020-02-08

Expiry Date: 2023-02-07

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Certificate No: **MD 577118**

Location

Joint Stock Company
"Ryazan State Instrument-
Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Kasimov Instrument-Making
Enterprise-Branch Ryazan State
Instrument-Making Enterprise
3, Industrialnaya Str.
391300 Kasimov
Russian Federation

Registered Activities

Manufacture, installation, distribution and servicing of active medical devices for ophthalmology.

Производство, инсталляция, продажи и сервисное обслуживание активных медицинских изделий для офтальмологии.

Manufacture, installation, distribution and servicing of active medical devices for magnetic field therapy and sterilizers.

Производство, инсталляция, продажи и сервисное обслуживание активных медицинских изделий для магнитной терапии и стерилизаторов.



Original Registration Date: 2016-06-23

Latest Revision Date: 2020-01-24

Effective Date: 2020-02-08

Expiry Date: 2023-02-07

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 577120**

Issued To:

**Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

In respect of:

Manufacture, final inspection and test of intraocular pressure tonometers.**Производство, выходной контроль и тестирование тонометров внутриглазного давления.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-27**Date: **2020-04-24**Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
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EC Certificate - Production Quality Assurance

Supplementary Information to CE 577120

Issued To:

**Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1105 MDS 7010	Tonometer of intraocular pressure	NA for class IIa devices

First Issued: **2016-06-27**

Date: **2020-04-24**

Expiry Date: **2024-05-26**

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Page 2 of 2

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 577120**
Date: **2020-04-24**
Issued To: **Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

Subcontractor:

Tonom GmbH
Mergelberg 115 A
48161 Münster
Germany

Service(s) supplied

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 577120**
Date: **2020-04-24**
Issued To: **Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation**

Date	Reference Number	Action
27 June 2016	8536503	First issue. Transfer from another Notified Body.
04 November 2016	8633374	Certificate Renewal
07 February 2019	8862697	Traceable to NB 0086.
Current	9759584	Scope reduction in order to remove (magnetic field therapy devices). Removal of critical location (Kasimov Instrument-Making Enterprise). Addition of device table.

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Joint Stock Company "Ryazan State
Instrument-Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Holds Certificate Number:

MD 577118

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture, installation, distribution and servicing of active medical devices for ophthalmology, magnetic field therapy and sterilizers.

Производство, инсталляция, продажа и сервисное обслуживание активных медицинских изделий для офтальмологии, магнитной терапии и стерилизаторов.

Previous certificate expired on 07/11/2016

Предыдущий срок действия сертификата истек на 07/11/2016

Recertification audit ended 19/01/2017

Ресертификационный аудит закончился 19/01/2017

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-23

Latest Revision Date: 2019-02-23

Effective Date: 2017-02-08

Expiry Date: 2020-02-07



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Certificate No: **MD 577118**

Location	Registered Activities
Joint Stock Company "Ryazan State Instrument- Making Enterprise" 32, Seminarskaya Str. 390000, Ryazan Russian Federation	Manufacture, installation, distribution and servicing of active medical devices for ophthalmology. Производство, инсталляция, продажа и сервисное обслуживание активных медицинских изделий для офтальмологии.
Kasimov Instrument-Making Enterprise-Branch Ryazan State Instrument-Making Enterprise 3, Industrialnaya Str. 391300 Kasimov Russian Federation	Manufacture, installation, distribution and servicing of active medical devices for magnetic field therapy and sterilizers. Производство, инсталляция, продажа и сервисное обслуживание активных медицинских изделий для магнитной терапии и стерилизаторов.

Original Registration Date: 2016-06-23

Latest Revision Date: 2019-02-23

Effective Date: 2017-02-08

Expiry Date: 2020-02-07

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Joint Stock Company
"Ryazan State Instrument-
Making Enterprise"
32, Seminarskaya Str.
390000, Ryazan
Russian Federation

Holds Certificate Number:

FM 577117

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**Production, installation, distribution and servicing of medical devices.
производство, инсталляцию, сервисное обслуживание и продажу медицинских изделий.**

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2006-11-08

Latest Revision Date: 2018-08-15

Effective Date: 2017-11-08

Expiry Date: 2020-11-07



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Приложение 3			Страница 8 / 8

Certificate No: FM 577117

Location	Registered Activities
Joint Stock Company "Ryazan State Instrument- Making Enterprise" 32, Seminarskaya Str. 390000, Ryazan Russian Federation	Production, installation, distribution and servicing of medical devices. производство, инсталляцию, сервисное обслуживание и продажу медицинских изделий.
Kasimov Instrument-Making Enterprise-Branch Ryazan State Instrument-Making Enterprise 3, Industrialnaya Str. 391300 Kasimov Russian Federation	Production, installation, distribution and servicing of medical devices. производство, инсталляцию, сервисное обслуживание и продажу медицинских изделий.

Original Registration Date: 2006-11-08

Latest Revision Date: 2018-08-15

Effective Date: 2017-11-08

Expiry Date: 2020-11-07

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