

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**

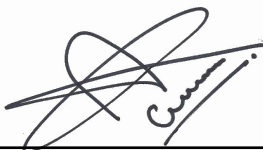
In respect of:

Manufacture, final inspection and test of intraocular pressure tonometers and magnetic field therapy devices.

Производство, выходной контроль и тестирование тонометров внутриглазного давления и аппаратов для магнитной терапии.

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):



Albert Roossien, Regulatory Lead

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

Date: **2019-02-07**

Expiry Date: **2021-11-07**

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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.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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| Subcontractor: | Service(s) supplied |
|--|----------------------------|
| "Kasimov Instrument-Making Enterprise"- -Branch "Ryazan State Instrument- Making Enterprise" 3, Industrialnaya Str. 391300 Kasimov Russian Federation | Manufacture |
| Tonom GmbH Mergelberg 115 A 48161 Münster Germany | EU Representative |

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EC Certificate - Production Quality Assurance Certificate History

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| Date | Reference Number | Action |
|------------------|------------------|---|
| 27 June 2016 | 8536503 | First issue. Transfer from another Notified Body. |
| 04 November 2016 | 8633374 | Certificate Renewal |
| Current | 8862697 | Traceable to NB 0086. |

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