



## EC Certificate - Production Quality Assurance

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

No. Issued To: CE 583051 Institute of Practical Psychophysics Ltd 1-ya Proizvodstvennaya 2 Omsk 644031 Russian Federation

In respect of:

#### The manufacture of Bio-resonance diagnostic hardware system "Metatron"

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: 30 March 2016

Date: 30 March 2016

Expiry Date: 20 February 2018

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





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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 583051

Date:

- - - - - -

Issued To:

Institute of Practical Psychophysics Ltd 1-ya Proizvodstvennaya 2 Omsk 644031 Russian Federation

#### Subcontractor:

Institute of Practical Psychophysics Europe s.r.o. Karla Englise 3201/6 Smichov, Praha 5 150 00 Czech Republic Service(s) supplied

**EU Representative** 

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# EC Certificate - Production Quality Assurance **Certificate History**

Certificate No:

CE 583051

Date:

Issued To:

Institute of Practical Psychophysics Ltd 1-ya Proizvodstvennaya 2 Omsk 644031 **Russian Federation** 

Date	Reference Number	Action
30 March 2016	8433433	First issue, transfer from another Notified Body



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