

EC Certificate - Product Quality Assurance

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

No. CE 580365
Issued To: **OOO NPP TECHNOMEDICA**
Building 1, 43 Sel'skokhozyaystvennaya Street
129323 Moscow
Russian Federation

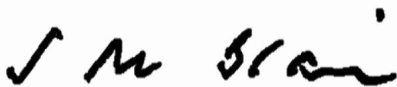
In respect of:

Final inspection of photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn PHAn-04-"NPP-TM" (BILITEST 2000).

Выходной контроль транскутанных скрининговых фотометрических автоматических двухканальных двухволновых анализаторов гипербилирубинемии у новорожденных АГФн-04-"НПП-ТМ" (БИЛИТЕСТ 2000).

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-04-25**Date: **2017-05-03**Expiry Date: **2022-05-15**

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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.

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List of Significant Subcontractors

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

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Date: **2017-05-03**
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Subcontractor:

Service(s) supplied

Wellkang Ltd
Suite B
29 Harley Street
London W1G 9QR
United Kingdom

EU Representative

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EC Certificate - Product Quality Assurance Certificate History

Certificate No: **CE 580365**
 Date: **2017-05-03**
 Issued To: **OOO NPP TECHNOMEDICA**
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Date	Reference Number	Action
25 April 2016	8503405	First issue, transfer from another Notified Body
03 May 2017	8675859	Certificate renewal.

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