

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 2797):



Albert Roossien, Regulatory Lead

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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.