Certificate

EC-Certificate

(Product quality assurance system)
according to Annex VI Medical Devices Directive 93/42/EEC

It is herewith confirmed by

BSI Group Deutschland GmbH
Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

in its function as Notified Body (0535), that the manufacturer

Joint-stock company "TECHNOMEDICA"
Starovatutinsky proezd 5, stroenie 3
129281 Moscow, Russia

concerning the medical device

"BILITEST 2000"
Photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn, PHAn-04-"NPP-TM"
UMDNS: 16-166, class IIa

fulfils the requirements according to Annex VI of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the final inspection of the specified devices.
For the placing on the market of class IIb products an Annex III certificate is required.

Report No.: SMO7763322
Certificate No.: CE580365

Current Issue Date: 30 August 2013

Certification Body

Notified by
Zentralstelle der Länder für Sicherheitstechnik
ZLS-NB-67/12

First Issue Date:
16 May 2012.

Based on periodical surveillance this certificate is valid until
15 May 2017.