Certificate

EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of
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:

ТРЕКПОР
ТЕХНОЛОДЖИ

"TRACKPORE TECHNOLOGY Corporation"
Priborostroiteley str. 3G, building 1
141980 Dubna, Moscow region, Russian Federation

concerning the medical device
(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding section 4) Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.
For the placing on the market of class III products an additional Annex II section 4 certificate is required.

The appendix is part of this certificate and contains 1 page.

Report No.: BQM08301DN01
Certificate No.: CE 576967

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

First Issue Date:
July 20, 2010.

Based on periodical surveillance this certificate is valid until
July 19, 2015.

Current Issue Date: August 30, 2013

Certification Body

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Appendix of EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC
Certificate No.: CE 576967

Medical devices of the manufacturer:

ТРЕКПОР
ТЕХНОЛОДЖИ

"TRACKPORE TECHNOLOGY Corporation"
Priborostroiteley str. 3G, building 1
141980 Dubna, Moscow region, Russian Federation

Name of product	Variant	Item	UMDNS	Class
Device for membranous plasmapheresis AMPld-"TT" HEMOFENIX			16-405	IIa

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

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Frankfurt am Main, August 30, 2013

Certification Body