

certificate



**EC-Certificate**

(full quality assurance system)  
according to annex II, section 3 of  
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

**EUROCAT Institute for  
Certification and Testing**

Quarat® Center \* Wittichstrasse 2  
D-64295 Darmstadt \* Germany  
Identification No. 0535,  
in its function as Notified Body,

that the manufacturer



**"TRACKPORE TECHNOLOGY  
Corporation"**

**Priborostroiteley str. 3G, building 1,  
141980 Dubna, Moscow region,  
Russian Federation**

concerning the medical device  
(products/variants specified in enclosure)  
fulfills the requirements according  
to Annex II, section 3,  
Medical Devices Directive 93/42/EEC.  
The manufacturer has established a quality  
assurance system for the design, production  
and final inspection of specified devices.

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

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

Report No.: BQM08301DN01  
**Certificate No.: CQ102011-II**

*Wilfried Bahelohay*  
Certification Body



**CE 0535**

Accreditation granted by  
Zentralstelle der Länder  
für Sicherheitstechnik



ZLS-ZQ-302/06

Darmstadt, 20 July 2010



certificate

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## Enclosure of EC-Certificate

(full quality assurance system)

according to annex II, section 3, Medical Devices Directive 93/42/EEC

**Certificate No.: CQ102011-II**

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Medical devices of the manufacturer:



**"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 AMPId-"TT" HEMOFENIX			16-405	Ila


# CE 0535

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## ZLS

ZLS-ZQ-302/06

Darmstadt, 20 July 2010



**Wilfried Babelovsky**  
Certification Body

