Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0063 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIb

Product category: **PRP Preparation Device**
Product commercial brand names: **Tropocells**
Mycells
Product types: **PPT-I Vacuum**
PPT-I Non vacuum
PPT-II Vacuum tube with sleeve filter aside
(For detailed list of variants refer to the annex; pages 1-2)

manufactured by company

Estar Technologies Ltd.
15 Hamerkava St., Holon 58851, Israel

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Reports Nos. 803601806/2013 and 803601807/2013, which are enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **27th January 2018** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Issued in Zlín, on 28th January 2013

Annex to EC CERTIFICATE
No. 13 0063 QS/NB

Issued for the company:

Estar Technologies Ltd.

15 Hamerkava St., Holon 58851, Israel

List of the variants covered by the Certificate:

Product category	PRP Preparation Device	
Product commercial brand name	Tropocells / Mycells	
Product type	PPT-I Vacuum	
Core Devices	*Description of separation tube*	*REF. No.*
	With gel / with ACD anticoagulant	12501002GLVAS
	With gel / with MACD anticoagulant	12521002GLVAS
	With gel / without anticoagulant	12121002GLVA
	Without gel / without anticoagulant	12991402GLA
Optional Accessories	*Name*	*REF. No.*
	Blood collection device (Vacu-10)	26754E
	Blunt needle	ESTBN18100E
	Sharp needle	ESTSN1890 / BDN304000
	Syringe	ESTS-SY10CCLS / BDS309628
	Plastic tube for waste collection	EST204-52

Product category	PRP Preparation Device	
Product Commercial Brand Name	Tropocells / Mycells	
Product type	PPT-I Non vacuum	
Core Devices	*Description of separation tube*	*REF. No.*
	With gel / with ACD anticoagulant	155030PL
	With gel / with MACD anticoagulant	155230PL
	With gel / without anticoagulant	151230PL
	Without gel / without anticoagulant	151030PL
Optional Accessories	*Name*	*REF. No.*
	Blood collection device with syringe	ESTP-SY60CCLSSV
	Blunt needle	ESTBN18100E
	Sharp needle	ESTSN1890 / BDN304000
	Syringe	ESTS-SY10CCLS / BDS309628
	Plastic tube for waste collection	EST204-52

Product category	PRP Preparation Device	
Product Commercial Brand Name	Tropocells / Mycells	
Product type	PPT-II Vacuum tube with sleeve filter aside	
Core Devices	*Description of separation tube*	*REF. No.*
	With gel / with ACD anticoagulant	1250VTSF10A
	With gel / with MACD anticoagulant	1252VTSF10A

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