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CE 1023

EC DECLARATION OF CONFORMITY

European Medical Device Directive 93/42/EEC

Manufacturer	**ESTAR TECHNOLOGIES Ltd.** Address: 15, Hamerkava St, Holon 5885111, Israel POB 2150, Holon 5812101, Israel
EC Authorized Representative	**OBELIS S.A** Corporate address: Bd. General Wohis, 53 1030 Brussels, Belgium
Notified Body	**ITC - The Institute for Testing and Certification, Inc.** Address: T. Bati 299, CZ-764 21 Zlin, Czech Republic

I, the undersigned, hereby declare that the distributed products specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificates", reference numbers 130063QS/NB / 130062 QS/NB / 101059 QS/NB/a / 101060 QS/NB/a, issued and delivered by ITC Notified Body, Identification Number 1023 Address: T. Bati 299, CZ--764 21 Zlin, Czech Republic in accordance with Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

This declaration is also supported by the Quality System Certification EN ISO 13485-2012, Certificate No. I8048 issued by IQC- Institute of Quality& Control Ltd, Address 6 Ravnitzky St. Shoam House, I.Z. Sgula, Petach-Tikva 49277, Israel, for manufacture and final inspection of the products concerned. This declaration is based on the conformity assessment of products to the requirements of Annex II.

Issue Place and Date: Holon, Israel 08/03/2015

Signature: _____

Estar Technologies LTD.
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Aaron Esteron

Name: Aaron Esteron
Position: CEO
Company: ESTAR TECHNOLOGIES Ltd.

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Annex: Product List

This product list below belongs to the Declaration of Conformity identified by ESTAR TECHNOLOGIES Ltd, and specifies the CE class IIb (PPT-I/II/III) and class IIa (Blunt/Sharp needle, Vacu-10 Blood Collection Device) products that ESTAR TECHNOLOGIES produces and distributes in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The following list identifies the products by model name and brand name:

No.	Device type	Commercial name	Class *	Rule	Short description and intended use
1	PPT-I	Tropocells / Mycells/ Cellenis	IIb	3	PRP Preparation Device
2	PPT-II	Tropocells / Mycells/ Cellenis	IIb	3	PRP Preparation Device
3	PPT-III	Tropocells / Mycells/ Cellenis	IIb	3	Closed System for PRP Preparation
4	Blunt needle	Tropocells / Mycells/ Cellenis	IIa	2	Blunt needle
5	Vacu-10 blood collection system	Tropocells / Mycells/ Cellenis	IIa	2	Blood collection System