Certificate

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-248.10.04

EC-Certificate

(Production quality assurance system)
according to annex V 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:

SET Medikal San. Ve Tic. A.Ş.
Osmangazi Mah. Mareşal Fevzi Çakmak Cd. No:18
34522 Esenyurt / İstanbul
Turkey

concerning the medical devices
Syringes and needles
(products/variants specified in appendix)

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

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

Report No.: SMO8106195
Certificate No.: CE 576078

First Issue Date:
December 19, 2008

Based on periodical surveillance this certificate is valid until December 18, 2018.

Current Issue Date: May 11, 2015

E. Schröder
Certification Body

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Appendix of EC-Certificate

(Production quality assurance system)
according to annex V of Medical Devices Directive 93/42/EEC
Certificate No.: CE 576078

Medical devices of the manufacturer:

SET Medikal San. Ve Tic. A.Ş.
Osmangazi Mah. Mareşal Fevzi
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Turkey

Name of product	Variant	Item	UMDNS	Class
Sterile Hypodermic Needles	---	---	12745	IIa
Tuberculin Syringes	---	---	35391	IIa
Insulin Syringes	---	---	35389	IIa
Syringes without Hypodermic Needles	---	---	35904	Is
2 Part Syringes with Hypodermic Needle	---	---	35904	IIa
3 Part Syringes with Hypodermic Needle	---	---	35904	IIa
Syringes for Blood Gas Analysis	---	---	16785	IIa
Syringes for Infusion Pumps	---	---	13217	IIa

With Class I products placed on the market in sterile condition and Class I devices with a measuring function application of the above mentioned Annex and the intervention by the notified body is limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

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E. Schröder

Frankfurt am Main, May 11, 2015

Certification Body