



Certificate

BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

herewith confirms, that the company

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

has established a **quality management system**
for the

**Development, manufacturing, sales
and distribution of syringes with and
without hypodermic needles,
hypodermic needles, spinal needles
(see enclosure).**

An audit has provided evidence that the quality
system is in compliance with the requirements of

DIN EN ISO 13485 : 2012
(EN ISO 13485 : 2012 + AC : 2012).

Report No.: SMO7876995

Certificate No.: MD 576077



First Issue Date:
December 19, 2008.

Based on periodical surveillance
this certificate is valid from December 19,
2013 until December 18, 2016.

Current Issue Date: December 17, 2013



Certification Body

Appendix of Certificate

according to DIN EN ISO 13485 : 2012 (EN ISO 13485 : 2012 + AC : 2012)

Certifikate No.: MD 576077

Location

Scope

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

Development, manufacturing, sales and distribution of syringes with and without hypodermic needles, hypodermic needles, spinal needles, syringes for blood gas analysis and the provision of a contract ethylene oxide sterilization service including validation and routine control in accordance with ISO 11135-1:2007



Deutsche
Akkreditierungsstelle
D-ZM-17232-02-01

Frankfurt am Main, December 17, 2013


Certification Body