

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

SET MEDIKAL Sanayi Ve Ticaret A.Ş.
Osmangazi Mah. Maresal Fevzi Çakmak Cd. No:18
34522 Esenyurt / İstanbul
Turkey

Holds Certificate Number:

MD 576077

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, sales and distribution of syringes with and without hypodermic needles, hypodermic needles, spinal needles and syringes for blood gas analysis.

The provision of a contract ethylene oxide sterilization service including validation and routine control in accordance with ISO 11135:2014.

Previous certificate expired on 16/06/2019
Recertification audit ended on 26/04/2019



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-17

Latest Revision Date: 2019-07-13

Effective Date: 2019-07-13

Expiry Date: 2022-06-16

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