



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 / Istanbul 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

Expiry Date: 2022-06-16

Effective Date: 2019-07-13

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online.

Printed copies can be validated at www.bsigroup.com/ClientDirectory