

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 576078**
Issued To: **SET MEDIKAL Sanayi Ve Ticaret A.Ş.**
Osmangazi Mah. Maresal Fevzi Çakmak Cd. No:18
34522 Esenyurt / İstanbul
Turkey

In respect of:

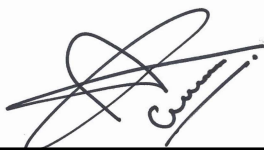
Manufacture of single use syringes with needles and single use hypodermic needles.

Those aspects of Annex V concerned with securing and maintaining the sterility of sterile single use syringes.

Those aspects of Annex V related to metrology in the manufacture of single use syringes.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-06-24**

Date: **2019-03-04**

Expiry Date: **2023-12-18**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 576078

Issued To:

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

| Number | Device Name | Intended purpose per IFU |
|--------------------------|---------------------------------------------|--------------------------|
| Class IIa | | |
| MD 0102 | Sterile Hypodermic Needles | --- |
| MD 0102 | Syringes for Infusion Pumps | --- |
| MD 0102 | 2 Part Syringes with Hypodermic Needle | --- |
| MD 0102 | 3 Part Syringes with Hypodermic Needle | --- |
| MD 0102 | Tuberculin Syringes with Needle | --- |
| MD 0102 | Insulin Syringes with Needle | --- |
| MD 0102 | Syringes for Blood Gas Analysis with Needle | --- |
| Class Is & Im | | |
| MD 0102 | Syringes without Hypodermic Needles | --- |

First Issued: **2016-06-24**

Date: **2019-03-04**

Expiry Date: **2023-12-18**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 576078**
Date: **2019-03-04**
Issued To: **SET MEDIKAL Sanayi Ve Ticaret A.Ş.**
Osmangazi Mah. Maresal Fevzi Çakmak Cd. No:18
34522 Esenyurt / Istanbul
Turkey

| Date | Reference Number | Action |
|------------------|------------------|----------------------------------------------------------------|
| 24 June 2016 | 8524044 | First issue. Transfer from another Notified Body. |
| 18 December 2018 | 9683500 | Certificate renewal. Addition of supplementary information. |
| Current | 9676033 | Traceable to NB 0086. |

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.