

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 / Istanbul
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**

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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.

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Supplementary Information to CE 576078

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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	---

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Page 2 of 2

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Certificate History

Certificate No: **CE 576078**
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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.

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Page 1 of 1

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