

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 573492**

Issued To:

**Sanlilar Tibbi Cihazlar Medikal
Kimya San. Tic. LTD. STI
10018 sk. No: 7 ITOB Organize Sanayi Bölgesi
Tekeli Izmir
35477
Turkey**

In respect of:

Design, development and manufacture of sterile dental implants and non-sterile abutments, surgical instruments, and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-12-14**Date: **2019-05-08**Expiry Date: **2021-02-22**

...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.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 573492**
Date: **2019-05-08**
Issued To: **Sanlilar Tibbi Cihazlar Medikal
Kimya San. Tic. LTD. STI
10018 sk. No: 7 ITOB Organize Sanayi Bölgesi
Tekeli Izmir
35477
Turkey**

Subcontractor:**Service(s) supplied**

Gamma-Pak Sterilizasyon
Sanayi ve Ticaret A.S.
Çerkezköy Organize Sanayi Bölgesi
Çerkezkoy O.S.B G.O. Pasa Mah. No6
Çerkezköy
59500
Turkey

Gamma Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 573492**
 Date: **2019-05-08**
 Issued To: **Sanlilar Tibbi Cihazlar Medikal
 Kimya San. Tic. LTD. STI
 10018 sk. No: 7 ITOB Organize Sanayi Bölgesi
 Tekeli Izmir
 35477
 Turkey**

Date	Reference Number	Action
14 December 2015	8427286	First Issue - transfer from another Notified Body
18 February 2016	8482721	Certificate Renewal Scope clarification to include 'sterile' and 'non-sterile'
18 February 2019	8486760	Traceable to NB 0086.
Current	9671611	Addition of NucleOSS Surgical Instruments.

...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.