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**

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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 Bolgesi Cerkezkoy O.S.B G.O. Pasa Mah. No6 Çerkezköy 59500 Turkey	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 573492**

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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.