

EC Certificate - Production Quality Assurance

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

No.**CE 77029**

Issued To:

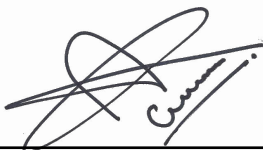
**Kardinero Medikal Sistemler Sanayi ve
Ticaret Anonim Sirketi
Üniversiteler Mah. Ihsan Dogramaci Bulv. No. 29
ODTU Teknokent Gumus Blok BK-7/B
Cankaya
Ankara
06800
Turkey**

In respect of:

The manufacture of Class IIa PC based ECG systems and ECG stress test systems with treadmills

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: **2003-11-12**Date: **2019-02-27**Expiry Date: **2023-11-11**

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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 77029

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06800
Turkey**

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1302	EKG Master USB Kit	Hardware and software for electrocardiography recording; to be installed and connected to a PC via USB port to use in diagnosis of cardiac diseases.
MD 1302	EKG Master USB ECG System	For electrocardiography recording to use in diagnosis of cardiac diseases
MD 1302	TM Pro Series Treadmill	Treadmill to be used for ECG Stress Testing with a Stress ECG device
MD 1302	ars-EFOR ECG Stress Test System with Treadmill	For electrocardiography recording and reporting during exercise

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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.

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

List of Significant Subcontractors

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

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ODTU Teknokent Gumus Blok BK-7/B
Cankaya
Ankara
06800
Turkey

Subcontractor:**Service(s) supplied**

Kardinero Medikal Sistemler Sanayi ve Ticaret Anonim Sirketi
Gazi Mahallesi, Polatli Cd. No:73
Yenimahalle
06560
Ankara
Turkey

Manufacture

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 77029**
 Date: **2019-02-27**
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 Cankaya
 Ankara
 06800
 Turkey**

Date	Reference Number	Action
12 November 2003		Original Issue.
07 February 2006		Clarification of scope with the insertion of 'treadmills'.
29 November 2006		Reissue of certificate due to change of company address.
13 November 2008	7101741	Certificate renewal.
12 September 2013	8015531	Certificate renewal. Change of company address from Gersan Sitesi 656 to Gersan Sitesi 2310/1 due to street renumbering.
11 July 2014	8169410	Change of company name and address from Tepas Tibbi ve Elektronik Ürünler San.ve Tic. A.S., Gersan Sitesi 2310/1 Sokak No:45, Ergazi, Ankara 06370 to Kardiosis Tibbi ve Elektronik Ürünler San.ve Tic. A.S., Üniversiteler Mah.Ihsan Dogramaci, Bulvari Silikon Blok K:1-4 Teknokent, ODTÜ, Cankaya/Ankara 06800 and addition of the Kardiosis Tibbi ve Elektronik Ürünler San.ve Tic. A.S., Gersan Sitesi 2310/1 Sokak No:45, Ergazi, Ankara 06370 site as a significant subcontractor for manufacture.

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Page 1 of 2

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 Cankaya
 Ankara
 06800
 Turkey**

Date	Reference Number	Action
21 February 2019	8905385	Change of name from Kardiosis Tibbi ve Elektronik Ürünler to Kardinero. Change of address from San. Ve Tic. A.S. Gersan Sitesi 2310/1 Sokak No:45 Ergazi Ankara 06370,Turkey to Üniversiteler Mah. Ihsan Dogramaci Bulv. No. 29, ODTU Teknokent Gumus Blok BK-7/B, Cankaya, 06800, Ankara,Turkey. Change of location of site for production: Gazi Mahallesi, Polatli Cd. No:73, Yenimahalle, 06560, Ankara, Turkey. Adding product table on the certificate.
Current	7780216	Traceable to NB 0086.