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

29/09/2023

Notified Body Confirmation Letter

Reference: EU2023-607/698006

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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TR-MF-000014932

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Kardinblu ECG	Class IIa	EKG Master USB Kit	Certificate CE 77029; 2797
Ars-EFOR ECG Stress Test with Treadmill	Class IIa	Ars-EFOR ECG Stress Test System with Treadmill	Certificate CE 77029; 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/09/29	Initial issue

By Royal Charter

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**
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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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EC Certificate - Production Quality Assurance

Supplementary Information to CE 77029

Issued To:

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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

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

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By Royal Charter

EC Certificate - Production Quality Assurance

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:

Certificate No:	**CE 77029**
Date:	**2019-02-27**
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**

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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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 Tepa Tibbi ve Elektronik Uriinler San.ve Tlc. A.S., Gersan Sitesi 2310/1 Sokak No:45, Ergazi, Ankara 06370 to Kardiosis Tlbbi ve Elektronik Ürünier San.ve Tic. A.S., Universiteler Mah.Ihsan Dogramaci, Bulvari Silikon Blok K:1-4 Teknokent, ODTÜ, Cankaya/Ankara 06800 and addition of the Kardiosis Tlbbi ve Elektronik Ürünier San.ve Tic. A.S., Gersan Sitesi 2310/1 Sokak No:45, Ergazi, Ankara 06370 site as a significant subcontractor for manufacture.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 77029**

Date: **2019-02-27**

Issued To: **Kardinero Medikal Sistemler Sanayi ve Ticaret Anonim Sirketi**
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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.