EC Certificate - Full Quality Assurance System

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

No. **CE 691292**

Issued To: **MEDIANA Co., Ltd.**
132, Donghwagongdan-ro
Munmak-eup
Wonju-si
Gangwon-do
26365
Republic of Korea

In respect of:

The design and manufacture of defibrillators, Patient Monitors, Central Monitoring System, Electrocardiograph (ECG), and Body Composition Analyzer.

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: **2018-05-22** Date: **2020-03-23** Expiry Date: **2023-11-05**

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Supplementary Information to CE 691292

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Class IIb		
GMDN	Device or Generic Device Group	Intended purpose as per IFU
33586	Patient monitor	The monitor is intended to be used to monitor Electrocardiography (ECG), Heart rate (HR), Non-invasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO2), Pulse rate (PR), Respiration rate (RR), Temperature (Temp), Capnography (EtCO2 and InCO2), Invasive blood pressure (IBP), Bispectral Index (BIS) and/or Multi gas and for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist. The vital sign monitor is only suitable for single measurement.
36870	Central Monitoring System	The intended use of the CMS is to display physiologic waves, parameters, and trends, format data for strip chart recordings and printings, and provide the annunciation of alarms from other networked Patient Monitor or Defibrillators/Monitors at a centralized location. The CMS provides for the retrospective review of alarms, physiologic waves and parameters from its database. The CMS is used in all areas of a hospital and hospital-type facilities and it is not intended to use at home environments. Users should be skilled at the level of a technician, doctor, nurse or medical specialist.

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47910	Automated External Defibrillator	The AED is intended to be used to treat someone who is unresponsive, non-breathing and pulseless for the adult and pediatric in all area of a hospital, pre-hospital, public access, alternate care and home healthcare environment. AED is designed to easy to use.
17882	Defibrillator/Monitor	The defibrillator/monitor is intended for use by trained medical technician, doctor, nurse or medical specialist in outdoor and indoor emergency care settings including air and ground ambulances within the environmental conditions specified. Manual and Automated external defibrillation, External pacing, Diagnostic electrocardiography (12-lead ECG) are intended for use on adult and pediatric patients. The other monitoring functions, Electrocardiography (ECG), Heart Rate(HR), Non-invasive blood pressure (NIBP), Functional arterial oxygen saturation (SpO2), Respiration (RESP), Temperature (TEMP) and/or Invasive blood pressure (IBP) are intended for use on adult, pediatric and neonatal patients. End tidal CO2 (EtCO2) are intended for use on adult, pediatric and infant patients.
Class IIa		
NBOG code	Device or Device subcategory	----
MD1302	Electrocardiograph (ECG)	----
MD1301	Body Composition Analyzer	----

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By Royal Charter

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List of Significant Subcontractors

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

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Issued To:	**MEDIANA Co., Ltd.** **132, Donghwagongdan-ro** **Munmak-eup** **Wonju-si** **Gangwon-do** **26365** **Republic of Korea**

Subcontractor:	**Service(s) supplied**
Obelis s.a Bd. Général Wahis 53 1030 Brussels Belgium	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
22 May 2018	8918854	First Issue. Transfer from another Notified Body.
05 November 2018	9664401	Certificate Renewal.
26 February 2019	8942092	Traceable to NB 0086.
Current	3083607	Certificate re-issue due to addition of Body Composition Analyzer in the scope of the certificate. Deletion of EU representative page as now only single EU representative is used. Addition of product list. Deletion of Medigate Inc from significant subcontractor list.