DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 40662-2008-CE-KOR-NA Rev.5.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Mediana Co., Ltd.

Gangwon-do, Korea

for design, production and final product inspection/testing of

Defibrillators

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 19 December 2013

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
05 November 2018

Angela Lanna
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

DET NORSKE VERITAS 1864

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate	2008-11-05
1.0	Extension of scope – new product added	2011-11-16
2.0	Extension of scope - new product added	2012-03-05
3.0	Extension of scope - new model added	2013-04-25
4.0	Extension of scope - new model added (in bold) and New EU Representative added (in bold)	2013-06-27
5.0	**Recertification** **Extension of scope - new model added (in bold)** **Address changed; based on street names** **New EU Representative added (in bold)**	**2013-11-05**

Products covered by this Certificate

Product Description	Product Name	Class
Automated External Defibrillator	• HeartOn A10 • A10-NR • **Care Vision DA10** • HeartOn A15	IIb
Defibrillator/Monitor	• D500 • M420	

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

EU Representative

HeartOn A10, D500, HeartOn A15:
OBELIS S.A, Bd. Général Wahis, 53, 1030 Brussels, Belgium

A10-NR:
BLOSTRUPMOEN, Postboks 113 – 2071 Råholt, Bønsdalsveien 32 – 2073 BØN, Norway

Care Vision DA10:
MBNet AG, Trockenloostrasse 29, 8105 Regensdorf, Switzerland

M420:
Metrax GmbH, Rheinwaldstr. 22, D-78628 Rottweil, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 37490-2008-AQ-KOR-NA

This is to certify that the Management System of

Mediana Co., Ltd.

132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

has been found to conform to the standard:

ISO 13485:2003 / NS-EN ISO 13485:2012

This Certificate is valid for the following product or service ranges:

Design, Manufacture and Servicing of Pulse Oximeters, Patient Monitors, Vital Sign Monitors, Defilbrillators, Ultrasound Systems, Laser Surgical Units and Light Units.

Initial Certification date:
19 July 2000

This Certificate is valid until:
14 October 2017

The audit has been performed under the supervision of
Seung Won Kim
Lead Auditor

NORWEGIAN ACCREDITATION
MSYS 002

Place and date:
Høvik, 15 October 2014

for the Accredited Unit:
DET NORSKE VERITAS CERTIFICATION AS, NORWAY

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info