Medical devices directive

The following information relates to the Medical Devices Directive:

EU Declaration of Conformity (Vicon Vero)

CE **0088**

Medical Devices Directive 93/42/EEC as amended by
EU Council Directive 2007/47/EC of 5th September 2007.
Electromagnetic Compatibility to EMC Directive 2014/30/EU
Electrical Safety to Low Voltage Directive 2014/35/EU.

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON VERO Cameras manufactured by VICON MOTION SYSTEMS LIMITED meet ANNEX V and VII Section 5 of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC in that the Quality Management System has been approved by Lloyd's Register Quality Assurance, a notified body of the European Union (Reg No. 0088) for the manufacture and support of the aforementioned CLASS 1(m) Medical device. Product configurations and software options (Vicon Vero cameras), detail the product configurations and software options that conform to the metrological requirements of the Directive.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

VICON MOTION SYSTEMS LIMITED has tested and demonstrated that all products of its own manufacture meet 2014/30/EU:

Electromagnetic Compatibility to:
EN60601-1-2:2007

General Requirements for Safety to:
Vero Cameras EN60601-1:2006 + A12:2014

Network Hub UL60950–1, 2nd Edition

Thomas Shannon, TD PhD FIE (Aust), CPEng (Biomed.)
Director of Compliance

20th April 2016

Not for use in an operating theater, anesthetic gas environment, or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, dust ingress, high vibration, sterile, or life- or safety-critical environments.

Product configurations and software options (Vicon Vero)

This topic provides information relating to the EU Declaration of Conformity (Vicon Vero cameras).

Conformity of the Metrological Performance of CLASS 1 Products Manufactured in Accordance with
Annex VII, Section 5 of the Medical Devices Directive 93/42/EEC of the 14th June 1993.
As amended by EU Council Directive 2007/47/EC of 5th September 2007.

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON VERO Cameras manufactured by VICON MOTION SYSTEMS LIMITED have been tested prior to shipment and meet the following metrological performance:

Measurement criteria

- Supporting software Blade 3.4 or later, Nexus 2.4 or later, and Tracker 3.3 or later.
- Resolution of the distance between the centers of two static 14 mm spherical markers located within a volume no less than 4 m x 4 m x 1.5 m to within 1 mm Mean; 1 mm Standard Deviation; sample size no less than 1,000.

CE Declaration of Conformity (Vicon Vantage)

CE **0088**

Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC.
Electromagnetic Compatability to EMC Directive 2004/108/EC.
Electrical Safety to Low Voltage Directive 2006/95/EC.

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON VANTAGE Cameras manufactured by VICON MOTION SYSTEMS LIMITED meets ANNEX V and VII Section 5 of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC in that the Quality Management System has been approved by Lloyd's Register Quality Assurance, a notified body of the European Union (Reg No. 0088) for the manufacture and support of the aforementioned CLASS 1(m) Medical device. Product configurations and software options (Vicon Vantage cameras) detail the product configurations and software options that conform to the metrological requirements of the Directive.

VICON MOTION SYSTEMS LIMITED has tested and demonstrated that all products of its own manufacture meet 2004/108/EC:

Electromagnetic Compatibility to:
EN60601-1-2:2007

General Requirements for Safety to:
Vantage Cameras EN60601-1:2006 + A12:2014

Network Hub UL60950–1, 2nd Edition

Thomas Shannon, TD PhD FIE (Aust), CPEng (Biomed.)
Director of Compliance

1st June 2015

Not for use in an operating theater, anesthetic gas environment, or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, dust ingress, high vibration, sterile, or life- or safety-critical environments.

Product configurations and software options (Vicon Vantage)

This topic provides information relating to the CE Declaration of Conformity (Vicon Vantage cameras).

Conformity of the Metrological Performance of CLASS 1 Products Manufactured in Accordance with
Annex V and VII, Section 5 of the Medical Devices Directive 93/42/EEC of 14th June 1993.
As amended by EU Council Directive 2007/47/EC of 5th September 2007.

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON VANTAGE Cameras manufactured by VICON MOTION SYSTEMS LIMITED have been tested prior to shipment and meet the following metrological performance:

Measurement criteria

- Supporting software Blade 3.2 or later, Nexus 2.2 or later, and Tracker 3.1 or later.

- Resolution of the distance between the centers of two static 14 mm spherical markers located within a volume no less than 4 m x 4 m x 1.5 m to within 1 mm Mean; 1 mm Standard Deviation; sample size no less than 1,000.

CE Declaration of Conformity (Vicon MX T-Series)

CE **0088**

Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC. Electromagnetic Compatability to EMC Directive 2004/108/EC. Electrical Safety to Low Voltage Directive 2006/95/EC.

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON MX T-Series motion capture system manufactured by VICON MOTION SYSTEMS LIMITED meets ANNEX V and VII Section 5 of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC in that the Quality Management System has been approved by Lloyd's Register Quality Assurance, a notified body of the European Union (Reg No. 0088) for the manufacture and support of the aforementioned CLASS 1 Medical device. Product configurations and software options (Vicon MX T-Series), details the product configurations and software options that conform to the metrological requirements of the Directive.

VICON MOTION SYSTEMS LIMITED has tested and demonstrated that all products of its own manufacture meet 2004/108/EC: MX T-Series Systems (MX Giganet based)

Electromagnetic Compatibility to:
EN60601-1-2:2007

Immunity to paragraph 6.2.3.1 to:
Immunity test level of 3V/m over 50 - 60 Hz

Electrical Safety of MxGiganet Power Supply Unit (Low Voltage Directive 2006/95/EC)
IEC 60601-1:1:1988 + A1:1991 + A2:1995 EN 60601-1:1990 A1,A2 and A13, excluding clause 36 and Korean national differences.

T.M.L. Shannon, TD, FIE (Aust), CPEng (Biomedical)
Director of Regulatory Compliance
1 July 2016

Not for use in an operating theater, anesthetic gas environment, or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, sterile, or life- or safety-critical environments.

Product configurations and software options (Vicon MX T-Series)

This topic provides information relating to the CE Declaration of Conformity (Vicon MX T-Series).

Conformity of the Metrological Performance of CLASS 1 Products in accordance with Annex V and VII Section 5 of the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC

We, Vicon Motion Systems Limited
Unit 14 Minns Estate
Oxford OX2 0JB
United Kingdom

declare that the VICON MX T-Series motion capture system manufactured by VICON MOTION SYSTEMS LIMITED has been tested prior to shipment and meets the following metrological performance:

- Resolution of the distance between the centers of two static 14 mm spherical markers located within a volume no less than 4 m x 4 m x 1.5 m to within 1 mm Mean; 1 mm Standard Deviation; sample size no less than 1,000
- Resolution of a given analog voltage to within +/-20 mV RMS within the following configurations and constraints:
    - No fewer than two cameras of any variant fully viewing static markers
    - Independent of lens and strobe variants fitted to each camera
    - Controlled lighting (no greater than 100 lux) and temperature (17-25° C)
    - Single termination to each analog input
    - Testing using the following Vicon application software: Nexus Version 1.4 or later

Production quality assurance certificate

Lloyd's Register
LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Vicon Motion Systems Ltd t/a Vicon
14 Minns Business Park, West Way
Oxford
United Kingdom

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 4003146/B
Original Approval:	17 August 2006
Current Certificate:	3 April 2017
Certificate Expiry:	16 August 2018

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

Lloyd's Register LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE
CERTIFICATE LRQ 4003146/B SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Vicon Motion Systems Ltd t/a Vicon
14 Minns Business Park, West Way
Oxford
United Kingdom

Class I Measuring Products
Vicon MX+ System
ViconT-Series System
Vicon Vantage System
Vicon Vero
Vicon Vue

Schedule Issue: 02

Date of Schedule Issue: 3 April 2017

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom