

EC Declaration of Conformity



The EC Directive(s) covered by this Declaration

93/42/EEC COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, amended by 2007/47/EC

Manufacturer: View-M Technology Co., Ltd.
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The Products Covered by this Declaration

Product description: Visual Chart System

Type designation(s): VLC-1900

VLC-1900P

MDD (93/42/EEC) classification: Class I (Rule 12 of Annex IX, 93/42/EEC)

Conformity Assessment Procedure: Annex VII, 93/42/EEC

The Basis on which Conformity is being declared

The product identified above complies with the essential requirements of the above EC Directive(s) by meeting the following standards:

EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15004-1:2009	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
IEC 60601-1:2005/AMD1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
IEC 60601-1-6:2010/AMD1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366:2007/AMD1:2014	Medical devices - Application of usability engineering to medical devices
IEC 62304:2006	Medical device software - Software life-cycle processes
EN ISO 15223-1:2016	Symbols for use in the labelling of medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices

This Declaration of Conformity is based on the EC Directive 93/42/EEC, Annex VII.

We, View-M Technology Co., Ltd., hereby declare under our sole responsibility that the above mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

Validity of this Declaration: 07.11.2018 - 06.11.2020

Gyeonggi-do, 07.11.2018

Place, Date


Gi-Gon Kim, CEO /
View-M TeChnology Co., Ltd.