

# 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

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## The Products Covered by this Declaration

Product description: Self Vision Tester

Type designation(s): VAA-2000PS  
VAA-2000PSE

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
EN 60601-1:2006+AC+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007+AC:2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life-cycle processes
EN 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:** 19.05.2020 - 20.05.2021

Gyeonggi-do, 19.05.2020

**Place, Date**

  
Ki-Gon Kim, CEO  
View-M TeChnology Co., Ltd.