

DECLARATION OF CONFORMITY

We,

COPY

Manufacturer's name	Takagi Seiko Co., Ltd.
Address	330-2 Iwafune, Nakano-shi, Nagano-ken, 383-8585, Japan
European Representative	Takagi Ophthalmic Instruments Europe Ltd
Address	Citylabs (Former Royal Eye Hospital Building) Nelson Street, Manchester M13 9NQ United Kingdom

declare under our sole responsibility that the product

Product Name	Slitlamp Digital Imaging System
／Model No.	Slitlamp Microscope／700GL、2ZL Digital Camera／TD-10 Image Filing Software／EyeCAM
MDD Classification	Class I
Serial No.(sn) : mmyynnn	From SN.0415026～
Lot No.(Lot) : yymmnnn	
m : lower two figures of manufactured month	
y : lower two figures of manufactured year	
n : consecutive numbers	

following the provisions of EC Council Directive(s)

93/42/EEC Annex V (MDD)
2011/65/EU(RoHS)

Notified Body

Notified Body	N/A
Certificate	N/A

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to which this declaration relates is in conformity with the following standard(s) or other normative document(s)

93/42/EEC Annex V (MDD)

EN 980:2008

EN 1041:2008

EN 60601-1:2006

EN 60601-1-2:2007

EN 60601-1-6:2010

EN 62304:2006

EN 62366:2008

EN ISO 13485:2012


EN ISO 14971:2012

EN ISO 15004-1:2009

2011/65/EU(RoHS)

EN 50581:2012

Date of Issue	2015/9/24
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Signature	
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Printed Name	Masaki Kanai
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Title	Director, Quality Assurance Department
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