

Ref. No.: 09-M04-01

DECLARATION OF CONFORMITY

We

Manufacturer

Canon Inc.

30-2, Shimomaruko 3-chome, Ohta-ku, Tokyo 146-8501, Japan

Authorized

Canon Europa N.V.

representative in Europe

Bovenkerkerweg 59-61, 1185 EG Amstelveen, The Netherlands

declare under our sole responsibility that product

DIGITAL RETINAL CAMERA (model) CX-1

(Class I, Rule 12)

is (are) in conformity with the essential requirements (Annex I) of EC Directive(s)

93/42/EEC

by applying the following harmonized standards

EC Directive(s)	Reference of standard(s) and amendment(s)
93/42/EEC	EN60601-1: 1990 with the following amendment(s) to this standard A1: 1993, A2: 1995, A13: 1996
	IEC60601-1: 1988 with the following amendment(s) to this standard A1: 1991, A2: 1995
	EN60601-1-1: 2001, IEC60601-1-1: 2000, EN60601-1-2: 2001
	EN60601-1-4: 1996 with the following amendment(s) to this standard A1: 1999 EN60601-1-6: 2004
	EN ISO15004-1: 2006, EN ISO15004-2: 2007, EN ISO10940: 1998
	EN ISO 10993-1:2003/10993-5:1999/10993-10:2002 with the following amendment(s) to this standard A1:2006
	EN ISO14971: 2000 with the following amendment(s) to this standard A1: 2003 EN980: 2003, EN1041: 1998

Note:

1. The CE Marking is affixed from the year '09.
2. The CE Marking is effective by date of the ISO certificate (19.09.2013)
3. The quality system covering the production is implemented according to ISO 13485 or monitored based on appropriate measures.
4. Copies of the rating plates of these models are attached.

Date: July 4, 2009



HIDEKI HOSOYA

General Manager Medical Equipment Quality Administration Div.

Medical Equipment Group

Canon Inc.

RECORD OF DECLARATION OF CONFORMITY
FOR MEDICAL DEVICE

Date	Contents of Technical Report		QA System ISO13485	Essential Requirement	Comments
	Electrical Safety	EMC			
09-08-04	GM No.12018997 CB Ref. No. 129676 CB Cert. No. NO53210	TA5094083 (M09EMC012)	SX60022706 0001	July 28, 2009	<u>Suffix No. 01 is issued.</u> (Model CX-1 new registration)

PDF File: BA5-0552-000-DA01-01
EPS File: BA5-0552-000-DB01-01

100mm



Canon Digital Retinal Camera CX-1

100-240V ~ 50/60Hz 8-4A



See Accompanying Documents

CANON INC.
30-2, SHIMOMARUKO 3-CHOME, OHTA-KU,
TOKYO, JAPAN

MADE IN JAPAN

MANUFACTURED:

NO.

Zertifikat Certificate



Zertifikat Nr. *Certificate No.*
I 50161124

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0001

<i>Ihr Zeichen Client Reference</i>	<i>Unser Zeichen Our Reference</i>	<i>Ausstellungsdatum</i>	<i>Date of Issue</i> (day/mo/yr)
--	ZJL-CCH- 12018997 002	31.07.2009	

Genehmigungsinhaber License Holder
Canon Inc.
30-2, Shimomaruko 3-chome
Ohta-ku, Tokyo
146-8501 JAPAN

Fertigungsstätte Manufacturing Plant
CANON COMPONENTS, INC.
3461-1 Oaza-shichihongi
Kamisato-machi
Kodama-gun, Saitama
369-0393 JAPAN

Prüfzeichen Test Mark

Geprüft nach *Tested acc. to*

EN 60601-1:1990+A1+A2+A13
IEC 60601-1:1988+A1+A2
EN ISO 15004-1:2006



Dieses Zertifikat allein berechtigt den Inhaber nicht zur Anbringung der CE Kennzeichnung.
This certificate alone does not entitle the holder to attach the CE marking.

Zertifiziertes Produkt (Geräteidentifikation)
Certified Product (Product Identification)

Lizenzentgelte - Einheit
License Fee - Unit

Digitalisier-Gerät Digital Retinal Camera

UMDNS Code 16-419

Bezeichnung : Digital Retinal Camera CX-1
(Type Designation)

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Nennspannung : AC 100-240V
(Rated Voltage)

Nennfrequenz : 50/60Hz
(Rated Frequency)

Nennstrom : 8-4A
(Rated Current)

Klassifikationen : Schutzklasse I
MDD Klasse I, Regel 12
(Classifications : Protection Class I
MDD Class I, rule 12)

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ANLAGE (Appendix) : 1

Dem Zertifikat liegt unsere Prüf- und Zertifizierungsordnung zugrunde.
Das Produkt entspricht den o.g. Anforderungen, die Herstellung wird überwacht.
This certificate is based on our Testing and Certification Regulation. The product fulfills above mentioned requirements, the production is subject to surveillance.



Zertifizierungsstelle

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Fax: (+49/221)8 06 - 39 35 http://www.tuv.com/safety

Dipl.-Ing. M. Geiser