

Canon Inc. Kosugi Office
 9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501,
 Japan
 Phone : (03) 3758-2111

Ref. No.: M1TJ-18R012

EU DECLARATION OF CONFORMITY

We

Manufacturer: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japan

Importer in Europe: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, The Netherlands

declare under our sole responsibility that the product(s)

Product Name: DIGITAL RADIOGRAPHY

model: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)

-Included Wireless LAN Module; model BM70659

is(are) in conformity with the essential requirements of EU Directive(s) and Regulation(s)

2014/53/EU, 2011/65/EU, 93/42/EEC

by applying the following standards

EU Directive(s)	Reference of standard(s) and amendment(s)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:201112
93/42/EEC	-

Note:

1. The quality system covering the production is implemented according to ISO EN13485 or monitored based on appropriate measures.
2. The internal design control system is implemented according to ISO 14000-series and monitored based on appropriate measures.

Place : Kawasaki, Japan Date: 18/07/2018



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Administration Div.
 Medical Components Group
 Canon Inc.

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ НА ЕС

Ние

Производител: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Япония

Вносител в Европа: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Холандия

декларираме на своя собствена отговорност, че продуктът(ите)

Име на продукта: DIGITAL RADIOGRAPHYмодел: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Включен безжичен LAN модул: BM70659

е(са) в съответствие със съществените разпоредби на Директива(и) и Регламент(и)

2014/53/EC, 2011/65/EC, 93/42/EEC

чрез прилагане на следните стандарти

Директива(и) на ЕС	Позоваване на стандарт(и) и изменение(я)
2014/53/EC	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EC	EN50581:2012
93/42/EEC	-

Забележка:

1. Системата за качество, обхващаща производството, е внедрена съгласно серията стандарти ISO 13485 или се контролира въз основа на подходящи мерки.
2. Вътрешната система за контрол на проектирането е внедрена в съответствие със серията стандарти ISO 14000 и се контролира въз основа на подходящи мерки.

Място: Кавазаки, Япония

Дата: 18/07/2018

Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

EU-KONFORMITÄTSERKLÄRUNG

Wir,

Hersteller: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japan

Importeur in Europa: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Niederlande,

erklären unter unserer alleinigen Verantwortung, dass das (die) Produkt(e)

Produktname: DIGITAL RADIOGRAPHYModell: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-einschließlich WLAN-Modul: BM70659

den wesentlichen Anforderungen der EU-Richtlinie(n) und der (den) folgenden Vorschrift(en) entspricht (entsprechen)

2014/53/EU, 2011/65/EU, 93/42/EEC

durch die Anwendung der folgenden Normen

EU-Richtlinie(n)	Referenz für die Norm(en) und Änderung(en)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:2012
93/42/EEC	-

Hinweis:

1. Das Qualitätsmanagementsystem für die Produktion wurde entsprechend der ISO-13485-Normenreihe eingeführt und wird auf der Grundlage angemessener Maßnahmen überwacht.
2. Das Umweltmanagementsystem wurde entsprechend der ISO-14000-Normenreihe eingeführt und wird auf der Grundlage angemessener Maßnahmen überwacht.

Ort: Kawasaki, Japan Datum: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

Εμείς

Κατασκευαστής: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Ιαπωνία

Εισαγωγέας στην Ευρώπη: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Ολλανδία

δηλώνουμε με αποκλειστική μας ευθύνη ότι το προϊόν (ή τα προϊόντα)

Όνομα Προϊόντος: DIGITAL RADIOGRAPHYΜοντέλο: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)- Συμπεριλαμβανομένης Μονάδας Ασύρματου LAN: BM70659

είναι σε συμμόρφωση με τις βασικές απαιτήσεις της Οδηγίας(-ών) και Κανονισμού(-ών) της ΕΕ

2014/53/ΕΕ, 2011/65/ΕΕ, 93/42/ΕΕC

εφαρμόζοντας τα ακόλουθα πρότυπα

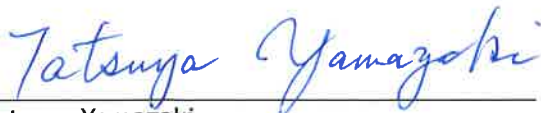
Οδηγία(-ες) ΕΕ	Αναφορά προτύπων και τροποποιήσεων
2014/53/ΕΕ	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/ΕΕ	EN50581:2012
93/42/ΕΕC	-

Σημείωση:

1. Το σύστημα ποιότητας που καλύπτει την παραγωγή υλοποιείται σύμφωνα με τη Σειρά ISO 13485 ή παρακολουθείται με βάση τα κατάλληλα μέτρα.
2. Το εσωτερικό σύστημα ελέγχου σχεδιασμού υλοποιείται σύμφωνα με τη σειρά ISO 14000 και παρακολουθείται με βάση τα κατάλληλα μέτρα.

Τόπος: Kawasaki, Ιαπωνία

Ημερομηνία: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

DECLARACIÓN DE CONFORMIDAD DE LA UE

Nosotros

Fabricante: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japón

Importador en Europa: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Países Bajos

declaramos bajo nuestra exclusiva responsabilidad que el (los) producto(s)

Nombre del producto: DIGITAL RADIOGRAPHY

modelo: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)

-Módulo LAN inalámbrico: BM70659 incluidos

está(n) en conformidad con los requisitos esenciales de la(s) Directiva(s) y Regulación(es) de la UE

2014/53/UE, 2011/65/UE, 93/42/EEC

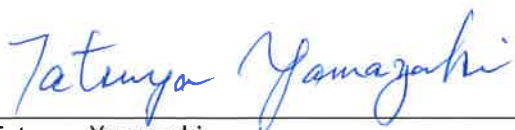
aplicando los siguientes estándares

Directiva(s) de la UE	Referencia del (de los) estándar(es) y enmienda(s)
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/UE	EN50581:2012
93/42/EEC	

Nota:

1. El sistema de calidad que cubre la producción se lleva a cabo según la serie ISO 13485 o es supervisado en base a medidas adecuadas.
2. El sistema de control de diseño interno es implementado en conformidad con la serie ISO 14000 y supervisado en base a medidas adecuadas.

Lugar: Kawasaki, Japón Fecha: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

DÉCLARATION DE CONFORMITÉ UE

Nous

Fabricant : CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japon

Importateur en Europe : Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Pays-Bas

déclarons sous notre seule responsabilité que le(s) produit(s)

Nom du produit: DIGITAL RADIOGRAPHY

modèle: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)

-Module LAN sans fil: BM70659 inclus

est/sont conforme(s) aux exigences essentielles de la/des directive(s) et de la/des Réglementation(s) de l'UE
2014/53/UE, 2011/65/UE, 93/42/EEC

en application des normes suivantes

Directive(s) UE	Référence de norme(s) et d'amendement(s)
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/UE	EN50581:2012
93/42/EEC	-

Remarque :

1. Le système de qualité couvrant la production est mis en œuvre selon la norme de série ISO 13485 et contrôlé sur la base de mesures appropriées.
2. Le système de contrôle de conception interne est mis en œuvre conformément à la norme de série ISO 14000 et contrôlé sur la base de mesures appropriées.

Lieu : Kawasaki, Japon Date : 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

EU IZJAVA O SUKLADNOSTI

Mi

Proizvođač: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japan

Uvoznik u Europi: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Nizozemska

izjavljujemo pod vlastitom odgovornošću da proizvod(i)

Naziv proizvoda: DIGITAL RADIOGRAPHY

model: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Uključeni modul bežičnog LAN-a: BM70659

je (su) u skladu s osnovnim zahtjevima EU Direktive(a) i Propisa

2014/53/EU, 2011/65/EU, 93/42/EEC

primjenom sljedećih standarda

EU Direktiva(e)	Referenca standarda i dopuna
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:2012
93/42/EEC	-

Bilješka:

1. Sustav kvalitete koji pokriva proizvodnju provodi se prema ISO 13485 seriji ili se prati na temelju odgovarajućih mjera.
2. Sustav upravljanja unutarnjim dizajnom provodi se prema ISO 14000-seriji i prati se na temelju odgovarajućih mjera.

Mjesto: Kawasaki, Japan

Datum: 18/07/2018

Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

EU MEGFELELŐSÉGI NYILATKOZAT

Mi,

termék gyártója: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japán

Európai importőr: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Hollandia

kizárólagos felelősségünkre kijelentjük, hogy a termék(ek)

terméknév: DIGITAL RADIOGRAPHYtípus: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-beépített vezeték nélküli LAN modul: BM70659megfelel(nek) a 2014/53/EU, 2011/65/EU, 93/42/EEC irányelv(ek) és szabályozás(ok) lényegi előírásainak, az alábbi szabványok és

irányelv(ek) alkalmazásával	Hivatkozott szabvány(ok) és kiegészítés(ek)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:2012
93/42/EEC	-

Megjegyzés:

1. A gyártást lefedő minőségbiztosítási rendszert az ISO 13485-es sorozat szerint alkalmazzák, vagy megfelelő intézkedésekkel felügyelik.
2. A belső kialakítású szabályozórendszert az ISO 14000-as sorozat szerint alkalmazzák és megfelelő intézkedésekkel felügyelik.

Hely: Kawasaki, Japán

Dátum: 2018/07/18



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

ESB SAMRÆMISYFIRLÝSING

Við

Framleiðandi: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japan

Innflytjandi í Evrópu: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Hollandi

lýsir hér með yfir á eigin ábyrgð að varan (vörunar)

Vöruheiti: DIGITAL RADIOGRAPHYgerð: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Innifalið þráðlaust staðarnet: BM70659

er (eru) í samræmi við grunnkröfurnar í tilskipun (tilskipanir) Evrópusambandsins og reglugerð (ir)

2014/53/ESB, 2011/65/ESB, 93/42/EEC

með því að beita eftirfarandi stöðlum

Tilskipun (tilskipanir) ESB	Tilvísun staðals (staðla) og breytingar (breytinga)
2014/53/ESB	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/ESB	EN50581:2012
93/42/EEC	-

Athugið:

- Gæðakerfið sem nær til framleiðslu er framleitt samkvæmt ISO 13485-röð eða fylgst er með viðeigandi ráðstöfunum.
- Innra hönnunarstýringakerfið er framleitt í samræmi við ISO 14000-röð og fylgst er með viðeigandi ráðstöfunum.

Staður: Kawasaki, Japan

Dagsetning: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

DICHIARAZIONE DI CONFORMITÀ UE

Noi

Produttore: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Giappone

Importatore in Europa: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Paesi Bassi

dichiariamo sotto la nostra esclusiva responsabilità che il/i prodotto/i

Nome del prodotto: DIGITAL RADIOGRAPHYModello: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Modulo LAN wireless: BM70659 inclusi

è/sono conformi ai requisiti essenziali della/e Direttiva/e UE e del/i Regolamento/i

2014/53/UE, 2011/65/UE, 93/42/EEC

con l'applicazione delle seguenti norme

Direttiva/e UE	Riferimento di norma/e ed emendamento/i
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/UE	EN50581:2012
93/42/EEC	-

Nota:

1. Il sistema di qualità che copre la produzione è realizzato secondo le norme ISO Serie 13485 o monitorato sulla base di misure appropriate.
2. Il sistema interno di controllo della progettazione è realizzato secondo le norme ISO Serie 14000 e monitorato sulla base di misure appropriate.

Luogo: Kawasaki, Giappone Data: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

ES ATITIKTIES DEKLARACIJA

Mes,

gamintojas CANON INC.,

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonija

importuotojas Europoje: Canon EUROPA N.V.,

Bovenkerkerweg 59, 1185 XB Amstelveen, Nyderlandai,

prisiimdami visą atsakomybę pareiškiame, kad gaminys (-iai)

gaminio pavadinimas: DIGITAL RADIOGRAPHYmodelis: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-įmontuotas belaidžio LAN modulis: BM70659

atitinka toliau nurodytos (-ų) ES direktyvos (-ų) ir reglamento (-ų) esminius reikalavimus

2014/53/EB, 2011/65/ES, 93/42/EEC

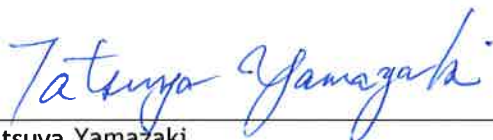
taikydama šiuos standartus

ES direktyva (-os)	Standarto (-ų) ir pakeitimo (-ų) nuoroda (-os)
2014/53/EB	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/ES	EN50581:2012
93/42/EEC	-

Pastaba:

1. Produkcijos kokybės sistema yra įdiegta pagal ISO 13485 seriją arba pagrįsta atitinkamomis priemonėmis.
2. Vidinė projektavimo kontrolės sistema yra įdiegta pagal ISO 14000 seriją ir yra stebima remiantis atitinkamomis priemonėmis.

Vieta: Kawasaki, Japonija Data: 2018/07/18



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

ES ATBILSTĪBAS DEKLARĀCIJA

Mēs

Ražotājs: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japāna

Importētājs Eiropā: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Nīderlande

ar pilnu atbildību deklarējam, ka izstrādājums (-i)

Izstrādājuma nosaukums: DIGITAL RADIOGRAPHYmodelis: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Iekļauts bezvadu LAN modulis: BM70659

atbilst būtiskām šādas (-u) ES direktīvas (-u) un regulas (-u) prasībām

2014/53/ES, 2011/65/ES, 93/42/EEC

piemērojot šādus standartus

ES direktīva (-s)	Atsauce uz standartu (-iem) un labojumu (-iem)
2014/53/ES	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/ES	EN50581:2012
93/42/EEC	-

Piezīme:

1. produkcijas kvalitātes nodrošināšanas sistēma ir ieviesta atbilstoši ISO 13485 sērijas standartu prasībām vai tiek uzraudzīta, veicot piemērotus pasākumus.
2. Iekšējā izstrādes kontroles sistēma ir ieviesta atbilstoši ISO 14000 sērijas prasībām un tiek uzraudzīta, veicot piemērotus pasākumus.

Vieta: Kawasaki, Japāna

Datums: 2018/06/13



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

EU-conformiteitsverklaring

Wij

Fabrikant: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japan

Importeur in Europa: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Nederland

verklaren onder onze eigen verantwoordelijkheid dat het (de) product(en)

Productnaam: DIGITAL RADIOGRAPHY

model: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)

-Inbegrepen draadloze LAN-module: BM70659

voldoet (voldoen) aan de essentiële vereisten van de EU-richtlijn(en) en verordening(en)

2014/53/EU, 2011/65/EU, 93/42/EEC

door de volgende normen toe te passen

EU-richtlijn(en)	Verwijzing naar norm(en) en amendement(en)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:2012
93/42/EEC	-

Opmerking:

1. Het kwaliteitssysteem voor de productie wordt uitgevoerd in overeenstemming met de ISO 13485-serie of gecontroleerd op basis van passende maatregelen.
2. Het interne ontwerpcontrolesysteem wordt geïmplementeerd volgens de ISO 14000-serie en gecontroleerd op basis van passende maatregelen.

Plaats: Kawasaki, Japan Datum: 18/07/2018

Tatsuya Yamazaki
General Manager
Medical Equipment Development Administration Div.
Medical Components Group
Canon Inc.

DEKLARACJA ZGODNOŚCI UE

My

Producent: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonia

Importer na Europę: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Holandia

oświadczamy na własną, wyłączną odpowiedzialność, że produkt(y)

nazwa produktu: DIGITAL RADIOGRAPHYmodel: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-dołączony moduł bezprzewodowej sieci LAN: BM70659

jest (są) zgodny(e) z zasadniczymi wymogami dyrektyw(y) i rozporządzenia (rozporządzeń) UE

2014/53/UE, 2011/65/UE, 93/42/EEC

poprzez zastosowanie następujących norm

Dyrektywa(y) UE	Odniesienie do norm(y) wraz ze zmianami
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/UE	EN50581:2012
93/42/EEC	-

Uwaga:

1. System jakości obejmujący produkcję został wdrożony zgodnie z normami ISO z serii 13485 lub jest monitorowany w oparciu o właściwe środki.
2. System wewnętrznej kontroli projektu został wdrożony zgodnie z normami z serii ISO 14000 i jest monitorowany w oparciu o właściwe środki.

Miejsce: Kawasaki, Japonia

Data: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

DECLARAȚIE DE CONFORMITATE UE

Noi

Producător: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonia

Importator în Europa: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Olanda

declarăm pe propria răspundere că produsul(ele)

Numele produsului: DIGITAL RADIOGRAPHY

Modelul: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-modul LAN fără fir: BM70659 incluse

este(sunt) în conformitate cu cerințele de bază ale Directivei(elor) și regulamentul(ele) UE

2014/53/UE, 2011/65/UE, 93/42/EEC

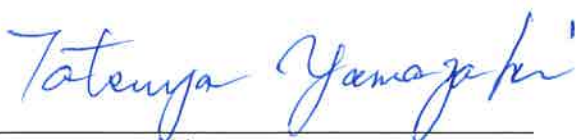
prin aplicarea următoarelor standarde

Directiva(ele) UE	Referința standardului(elor) și a amendamentului(elor)
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/UE	EN50581:2012
93/42/EEC	-

Notă:

1. Sistemul de calitate care acoperă producția este implementat în conformitate cu seria ISO 13485 sau monitorizat pe baza unor măsuri corespunzătoare.
2. Sistemul intern de control al proiectării este implementat în conformitate cu seria ISO 14000 și monitorizat pe baza unor măsuri corespunzătoare.

Locație: Kawasaki, Japonia Data: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

EÚ VYHLÁSENIE O ZHODE

My

Výrobca: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonsko

Dovozca v Európe: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Holandsko

na vlastnú zodpovednosť vyhlasujeme, že výrobok (výrobky)

Názov výrobku: DIGITAL RADIOGRAPHYmodel: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-zahrnutý modul bezdrôtovej siete LAN: BM70659

je (sú) v súlade so základnými požiadavkami smerníc EÚ a nariadením (nariadeniami)

2014/53/EÚ, 2011/65/EÚ, 93/42/EEC

použitím nasledovných noriem

smernice EÚ	Odkaz na normu (normy) a zmenu (zmeny)
2014/53/EÚ	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EÚ	EN50581:2012
93/42/EEC	-

Poznámka:

1. Systém kvality ktorý pokrýva výrobu je implementovaný podľa série ISO 13485 alebo monitorovaný na základe príslušných opatrení.
2. Interný systém kontroly dizajnu je realizovaný podľa série ISO 14000 a monitorovaný na základe príslušných opatrení.

Miesto: Kawasaki, Japonsko

Dátum: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

Izjava o skladnosti za EU

Mi

Proizvajalec: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonska

Uvoznik v Evropi: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Nizozemska

z izključno odgovornostjo izjavljamo, da je izdelek (so izdelki)

Ime izdelka: DIGITAL RADIOGRAPHYmodel: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7),
CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Vključen modul za brezžični LAN: BM70659

je(so) v skladu z osnovnimi zahtevami direktiv(e) in predpisa(ov) EU

2014/53/EU, 2011/65/EU, 93/42/EEC

z uporabo naslednjih standardov

Direktiva(e) EU	Sklicevanje na standard(e) in spremembo(e)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/EU	EN50581:2012
93/42/EEC	-

Opomba:

1. Sistem kakovosti, ki zajema proizvodnjo, se izvaja v skladu s serijo ISO 13485 ali spremlja na podlagi ustreznih ukrepov.
2. Notranji sistem nadzora oblikovanja se izvaja v skladu s serijo ISO 14000 in se spremlja na podlagi ustreznih ukrepov.

Kraj: Kawasaki, Japonska

Datum: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.

AB UYGUNLUK BEYANI

Biz

Üretici: CANON INC.

9-1, Imaikami-cho, Nakahara-ku, Kawasaki-shi, Kanagawa 211-8501, Japonya

Avrupa'daki İthalatçı: Canon EUROPA N.V.

Bovenkerkerweg 59, 1185 XB Amstelveen, Hollanda

beyan ederiz olarak tamamen kendi sorumluluğumuz altında

Ürün Adı: DIGITAL RADIOGRAPHYModel: CXDI-701G Wireless (WM5A5), CXDI-701C Wireless (WM5A6), CXDI-401G Wireless (WM5A7), CXDI-401C Wireless (WM5A8), CXDI-801G Wireless (WM5A9), CXDI-801C Wireless (WM5A10)-Kablosuz LAN Modülü: BM70659 dahil

ürünün(ürünlerin) 2014/53/AB, 2011/65/AB, 93/42/EEC no.lu AB Direktif(ler)inin ve Yönetmeliğinin(Yönetmeliklerinin) temel gerekliliklerine uygun olduğunu

aşağıdaki standartları uygulayarak

AB Direktifi(Direktifleri)	Standardın(Standartların) ve değişikliğin(değişikliklerin) referansı
2014/53/AB	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN62311: 2008
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
	EN301 489-1 V2.1.1
2011/65/AB	EN50581:2012
93/42/EEC	-

Not:

1. Üretimi kapsayan kalite sistemi, ISO 13485-Serisine göre uygulanmakta veya uygun önlemlere göre izlenmektedir.
2. İç tasarım kontrol sistemi, ISO 14000 serisine göre uygulanmakta ve uygun önlemlere göre izlenmektedir.

Yer: Kawasaki, Japonya

Tarih: 18/07/2018



Tatsuya Yamazaki

General Manager

Medical Equipment Development Administration Div.

Medical Components Group

Canon Inc.