

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: Flat Panel Detector

model: AR-C3543W, AR-C4343W

-Included Wireless LAN Module;model BM72065

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

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

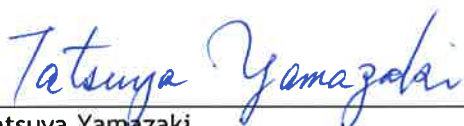
by applying the following standards

EU Directive(s)	Reference of standard(s) and amendment(s)
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN50566: 2017
	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	-

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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectorмодел: AR-C3543W, AR-C4343W-Включен безжичен LAN модул: BM72065

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
	EN50566: 2017
	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: Кавасаки, Япония Дата: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel DetectorModell: AR-C3543W, AR-C4343W-einschließlich WLAN-Modul: BM72065

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

Μοντέλο: AR-C3543W, AR-C4343W

- Συμπεριλαμβανομένης Μονάδας Ασύρματου LAN: BM72065

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

2014/53/ΕΕ, 2011/65/ΕΕ, 93/42/ΕΕC

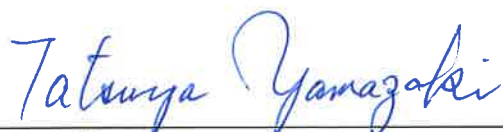
εφαρμόζοντας τα ακόλουθα πρότυπα

Οδηγία(-ες) ΕΕ	Αναφορά προτύπων και τροποποιήσεων
2014/53/ΕΕ	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

modelo: AR-C3543W, AR-C4343W

-Módulo LAN inalámbrico: BM72065 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

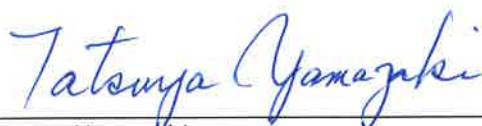
aplicando los siguientes estándares

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

modèle: AR-C3543W, AR-C4343W

-Module LAN sans fil: BM72065 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
	EN50566: 2017
	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 : 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectormodel: AR-C3543W, AR-C4343W-Uključeni modul bežičnog LAN-a: BM72065

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

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

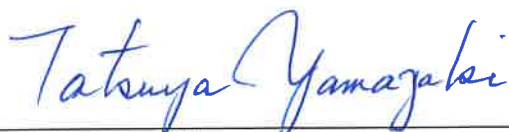
primjenom sljedećih standarda

EU Direktiva(e)	Referenca standarda i dopuna
2014/53/EU	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

típus: AR-C3543W, AR-C4343W

-beépített vezeték nélküli LAN modul: BM72065

megfelel(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
	EN50566: 2017
	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: 2019/10/24



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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 (vöurnar)

Vöruheiti: Flat Panel Detector
gerð: AR-C3543W, AR-C4343W
-Innifalið þráðlaust staðarnet: BM72065

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

Modello: AR-C3543W, AR-C4343W

-Modulo LAN wireless: BM72065 inclusi

è/sono conformi ai requisiti essenziali della/e Direttiva/e UE e del/i Regolamentoo/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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

modelis: AR-C3543W, AR-C4343W

-įmontuotas belaidžio LAN modulis: BM72065

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
	EN50566: 2017
	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: 2019/10/24



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectormodelis: AR-C3543W, AR-C4343W-Iekļauts bezvadu LAN modulis: BM72065

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
	EN50566: 2017
	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: 2019/10/24



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectormodel: AR-C3543W, AR-C4343W-Inbegrepen draadloze LAN-module: BM72065

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectormodel: AR-C3543W, AR-C4343W-dołączony moduł bezprzewodowej sieci LAN: BM72065

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

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

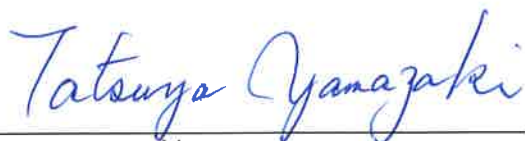
poprzez zastosowanie następujących norm

Dyrektywa(y) UE	Odniesienie do norm(y) wraz ze zmianami
2014/53/UE	EN300 328 V2.1.1
	EN301 893 V2.1.1
	EN50566: 2017
	EN60950-1: 2006 + Amd.11: 2009+Amd.1:2010+Amd.12:2011+Amd.2:2013
	EN301 489-17 V3.1.1
2011/65/UE	EN301 489-1 V2.1.1
	EN50581:2012
93/42/EEC	-

Uwaga:

- System jakości obejmujący produkcję został wdrożony zgodnie z normami ISO z serii 13485 lub jest monitorowany w oparciu o właściwe środki.
- 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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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(e)

Numele produsului: Flat Panel DetectorModelul: AR-C3543W, AR-C4343W-modul LAN fără fir: BM72065 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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

model: AR-C3543W, AR-C4343W

-zahrnutý modul bezdrôtovej siete LAN: BM72065

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detectormodel: AR-C3543W, AR-C4343W-Vključen modul za brezžični LAN: BM72065

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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki
 General Manager
 Medical Equipment Development Promotion 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: Flat Panel Detector

Model: AR-C3543W, AR-C4343W

-Kablosuz LAN Modülü: BM72065 dahilürünün(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
	EN50566: 2017
	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: 24/10/2019



Tatsuya Yamazaki

General Manager

Medical Equipment Development Promotion Div.

Medical Components Group

Canon Inc.