Philips Consumer Lifestyle B.V.

1914

(Document No.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed)

EU DECLARATION OF CONFORMITY

We, PHILIPS CONSUMER LIFESTYLE B.V.
(Company name)
TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS
(address)

declare under our responsibility that the product(s): DL8760

Philips
(brand name)

(Type version or model)

Philips upper arm blood pressure monitor
(product description)

to which this declaration relates is in conformity with the following harmonized standards:

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC
(Name and number)

and issued the certificate: 86443CE10 Revoked
(certificate number)

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18
(place,date)

A.Speelman, CL Compliance Manager
(signature, name and function)

Philips Consumer Lifestyle B.V.

1914

(Document No. /Bericht Nr.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed /Jahr der CE Zeichenerteilung)

EU DECLARATION OF CONFORMITY

(EG - Konformitätserklärung)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Name)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / Anschrift)

declare under our responsibility that the product(s) DL8760

erklären als Verantwortliche, daß folgende(s) elektrische(n) Produkt(e)

Philips

(brand name, Markenname)

(Type version or model, Typenbezeichnung oder Modell)

Philips upper arm blood pressure monitor

(product description, Produktbezeichnung)

to which this declaration relates is in conformity with the following harmonized standards:

(auf die sich diese Konformitätserklärung bezieht, allen nachstehenden hamonisierten Normen entspricht.)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Entsprechend den Bestimmungen der)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(und die gemäß eines Qualitätsystems produziert werden, dass mindestens der ISO 9001 oder CENELEC Permanent Documents entspricht)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(benannte Stelle) *(Name and number/ Name und Kennnummer)* *(ausgeführt)* *(description of intervention / Beschreibung des Verfahrens)*

and issued the certificate: 86443CE10 Revoked

(und stellen das Zertifikat) *(certificate number / Zertifikatnummer)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / Ort, Datum)

A.Speelman, CL Compliance Manager

(signature, name and function / Unterschrift, Name und Funktion des Unterzeichners)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Numéro du document)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Année/mois (aaaa/mm) au cours de laquelle le marquage CE a été apposé)

EU DECLARATION OF CONFORMITY

(DECLARATION DE CONFORMITE CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nom de l'entreprise)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresse)

declare under our responsibility that the product(s) DL8760

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

Philips

(brand name, nom de la marque)

(Type version or model, référence ou modèle)

Philips upper arm blood pressure monitor

(product description, description du produit)

to which this declaration relates is in conformity with the following harmonized standards:

(auquel cette déclaration se rapporte, est conforme aux normes harmonisées suivantes)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(conformément aux exigences essentielles et autres dispositions pertinentes de:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Et sont fabriqués conformément à une qualité au moins conforme à la norme ISO 9001 ou aux Documents Permanents CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(L'Organisme Notifié) *(Name and number/ nom et numéro)* *(a effectué)* *(description of intervention / description de 'intervention)*

and issued the certificate: 86443CE10 Revoked

(et a délivré le certificat) *(certificate number / numéro du certificat)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / lieu, date)

A.Speelman, CL Compliance Manager

(signature, name and function / signature, nom et fonction)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Documentnummer)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Jaar, maand waarin de CE markering is uitgegeven)

EU DECLARATION OF CONFORMITY

(Europeese Conformiteitsverklaring)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Bedrijfsnaam)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adres)

declare under our responsibility that the product(s) DL8760

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

Philips

(brand name, merknaam)

(Type version or model, typenummer of model)

Philips upper arm blood pressure monitor

(product description, productbeschrijving)

to which this declaration relates is in conformity with the following harmonized standards:

(waar deze verklaring betrekking op heeft voldoen aan de volgende geharmoniseerde standaarden)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(volgens de voorwaarden van:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(En worden geproduceerd volgens een kwaliteitsprogramma wat minimaal overeenkomt met ISO9001 of de CENELEC permanente documenten)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Notified Body) *(Name and number/ Naam en nummer)* *(heeft uitgevoerd)* *(description of intervention / uitgevoerd testprotocol)*

and issued the certificate: 86443CE10 Revoked

(en heeft een certificaat uitgegeven) *(certificate number / nummer van het certificaat)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / plaats, datum)

A.Speelman, CL Compliance Manager

(signature, name and function / handtekening, naam en functie)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Číslo zprávy)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Rok udělění známky CE)

EU DECLARATION OF CONFORMITY

(Prohlášení o shodě v EU)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Jméno)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresa)

declare under our responsibility that the product(s) DL8760

(Prohlašujeme na svou odpovědnost, že elektrický výrobek)

Philips

(brand name, značka)

(Type version or model, Typ verze nebo model)

Philips upper arm blood pressure monitor

(product description, popis výrobku)

to which this declaration relates is in conformity with the following harmonized standards:

(na nějž se toto prohlášení vztahuje, je ve shodě s následujícími harmonizovanými normami:)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Následovaných ustanoveními Směrnic:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(A jsou vyráběny v systému řízení kvality minimálně ve shodě s ISO 9001 nebo)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Kompetentní orgán) *(Name and number/ Název a číslo)* *(provedl)* *(description of intervention / popis operace)*

and issued the certificate: 86443CE10 Revoked

(a vydal certifikát,) *(certificate number / číslo certifikátu)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / místo, datum)

A.Speelman, CL Compliance Manager

(signature, name and function / podpis, jméno a funkce)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Rapportnummer)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Årstal for påhæftning af CE-mærkningen)

EU DECLARATION OF CONFORMITY

(EU KONFORMITETSERKLÆRING)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Virksomhedens navn)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresse)

declare under our responsibility that the product(s) DL8760

(Erklærer i henhold til vores ansvar, at de(t) elektriske produkt(er))

Philips

(brand name, navn på varemærke)

(Type version or model, type eller model)

Philips upper arm blood pressure monitor

(product description, produktbeskrivelse)

to which this declaration relates is in conformity with the following harmonized standards:

(til hvilke(t) denne erklæring relaterer sig, er i konformitet med følgende harmoniserede standarder)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Opfylder de ufravigelige krav og øvrige forskrifter i)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Og er produceret i en kvalitet, der, som minimum, opfylder kravene i ISO 9001-standarden eller CENELEC's permanente dokumenter)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Det Notificerede Organ) *(Name and number/ Navn og nummer)* *(har gennemført)* *(description of intervention / beskrivelse af intervention)*

and issued the certificate: 86443CE10 Revoked

(og udstedt erklæringen) *(certificate number / erklæringsnummer)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / sted, dato)

A.Speelman, CL Compliance Manager

(signature, name and function / Signatur, navn og titel)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Documento nº.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Año en el que se incluye el marcado CE))

EU DECLARATION OF CONFORMITY

(EU DECLARACIÓN CE DE CONFORMIDAD)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nombre compaña)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / dirección)

declare under our responsibility that the product(s): DL8760

(Declaramos bajo nuestra propia responsabilidad que el (los) producto(s):

Philips

(brand name, nombre de la marca)

(Type version or model, Referencia o modelo)

Philips upper arm blood pressure monitor

(product description, descripción del producto)

to which this declaration relates is in conformity with the following harmonized standards:

(Al que hace referencia esta declaración cumple con las siguientes normas armonizadas)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Siguiendo las disposiciones relativas a:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Y se fabrican conforme a una calidad al menos conforme a la norma ISO 9001 o a los Documentos Permanentes CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(El organismo notificado) *(Name and number/ Nombre y número)* *(realizador)☐* *(description of intervention / descripción de la intervención)*

and issued the certificate: 86443CE10 Revoked

(Y expidió el certificado) *(certificate number / número de certificado)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / lugar, fecha)

A.Speelman, CL Compliance Manager

(signature, name and function / firma, nombre y cargo)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Raportti nr.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / CE merkinnän myöntämisvuosi)

EU DECLARATION OF CONFORMITY

(Vaatimustenmukaisuusvakuutus)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nimi)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / Osoite)

declare under our responsibility that the product(s) DL8760

(Ilmoitus seuraavista vastuullamme olevista sähkötuotteista:)

Philips

(brand name, Brändinimi)

(Type version or model, Tyypi, versio tai malli)

Philips upper arm blood pressure monitor

(product description, Tuotekuvaus)

to which this declaration relates is in conformity with the following harmonized standards:

(Tämä vakuutus on yhdenmukainen seuraavien harmonisointistandardien kanssa)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Seuraavien määräysten mukaisesti)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Ja on tuotettu seuraavien laatujärjestelmien mukaisesti : ISO 9001 ja CENELEC asiakirjat)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Ilmoitettu laitos) *(Name and number/ Nimi ja numero)* *(suoritetaan)* *(description of intervention / toimenpiteen kuvaus)*

and issued the certificate: 86443CE10 Revoked

(Todistuksen antaja) *(certificate number / Sertifikaatin numero)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / paikka, päiväys)

A.Speelman, CL Compliance Manager

(signature, name and function / Allekirjoitus, nimi ja asema)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Jelentés száma)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / A CE jelzés feltüntetésének éve)

EU DECLARATION OF CONFORMITY

(EC MEGFELELŐSÉGI NYILATKOZAT)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Név)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / cím)

declare under our responsibility that the product(s) DL8760

(Felelőssége tudatában nyilatkozik, hogy az alábbi elektronikai termék(ek))

Philips

(brand name, márkanév)

(Type version or model, Típusváltozat vagy modell)

Philips upper arm blood pressure monitor

(product description, termék megnevezése)

to which this declaration relates is in conformity with the following harmonized standards:

(Az ezen nyilatkozatban foglaltak szerint megfelel(nek) a következő harmonizált szabványoknak)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Követve a következő ajánlásokat)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(legalább az ISO 9001-nek megfelelően vagy)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Bejelentett testület) *(Name and number/ Név és szám)* *(teljesítve)* *(description of intervention / intézkedés leírása)*

and issued the certificate: 86443CE10 Revoked

(és a kibocsátott tanúsítvány) *(certificate number / tanúsítvány száma)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / hely, dátum)

A.Speelman, CL Compliance Manager

(signature, name and function / aláírás, név és beosztás)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Report Numero)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Anno di apposizione della marcatura CE)

EU DECLARATION OF CONFORMITY

(DICHIARAZIONE DI CONFORMITA' CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / denominazione sociale)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / sede)

declare under our responsibility that the product(s): DL8760

(dichiara sotto la propria responsabilità che il /i Prodotto /i elettrico/i)

Philips

(brand name, marchio)

(Type version or model, modello o versione)

Philips upper arm blood pressure monitor

(product description, descrizione del prodotto)

to which this declaration relates is in conformity with the following harmonized standards:

(al quale la presente dichiarazione si riferisce è conforme alle seguenti norme tecniche armonizzate)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(secondo le disposizioni della)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(e i processi produttivi seguono un sistema qualità conforme almeno alla norma ISO 9001 o ai documenti permanenti CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(L'ente certificatore notificato) *(Name and number/ denominazione e numero)* *(ha eseguito)* *(description of intervention / descrizione dell'intervento)*

and issued the certificate: 86443CE10 Revoked

(ed emesso il certificato) *(certificate number / numero del certificato)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / luogo e data)

A.Speelman, CL Compliance Manager

(signature, name and function / firma , nome e funzione)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Pranešimo Nr.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Metai, kada CE patvirtino)

EU DECLARATION OF CONFORMITY

(EC ATITIKTIES DEKLARACIJA)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Pavadinimas)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresas)

declare under our responsibility that the product(s) DL8760

(Deklaruojame, kad elektronikos gaminys (-iai):)

Philips

(brand name, firmos ženklo pavadinimas)

(Type version or model, Tipas arba modelis)

Philips upper arm blood pressure monitor

(product description, gaminio aprašymas)

to which this declaration relates is in conformity with the following harmonized standards:

(Pagal šią deklaraciją atitinka toliau nurodytus standartus:)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Atitinka tokias nuostatas:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Pagaminta atitinkant visus kokybės reikalavimus pagal ISO 9001 ar CENELEC nuolatinius dokumentus)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Informuota įstaiga) *(Name and number/ Pavadinimas ir numeris)* *(atlikta)* *(description of intervention / intervencijos aprašymas)*

and issued the certificate: 86443CE10 Revoked

(Sertifikatas išleistas) *(certificate number / sertifikato numeris)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / vieta, data)

A.Speelman, CL Compliance Manager

(signature, name and function / parašas, vardas, pavardė ir pareigos)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Ziņojums Nr)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Gads kurā CE zīme ieviesta)

EU DECLARATION OF CONFORMITY

(EC deklarācija atbilstība)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / vārds)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adrese)

declare under our responsibility that the product(s) DL8760

(deklarēt zem vai atbildība ka, elektronisks produkts)

Philips

(brand name, fabrikas marka vārds)

(Type version or model, Tips, versija vai modelis)

Philips upper arm blood pressure monitor

(product description, produkta apraksts)

to which this declaration relates is in conformity with the following harmonized standards:

(Kam ši deklarācija atbilst ir apliecināt ar sekojošiem saskaņotiem standartiem)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Sekojot noteikumiem)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Tiek ražots zem kvalitātes sistēma kas ir apstiprināta ar ISO 9001 vai CENELEC pastāvošiem dokumentiem)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Reģistrēta galvenā daļa) *(Name and number/ vārds un numurs)* *(paveikts)* *(description of intervention / intervencijas apraksts)*

and issued the certificate: 86443CE10 Revoked

(Un izveido sertifikātu) *(certificate number / sertifikāta numurs)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / vieta, datums)

A.Speelman, CL Compliance Manager

(signature, name and function / parskts, vārds un amatpienākums)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Numer raportu)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Rok, w którym oznakowanie CE zostało umieszczone na wyrobie)

EU DECLARATION OF CONFORMITY

(DEKLARACJA ZGODNOŚCI UE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nazwa)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adres)

declare under our responsibility that the product(s) DL8760

(Deklarujemy na naszą odpowiedzialność, że urządzeni(e/a) elektryczne)

Philips

(brand name, marka)

(Type version or model, Typ lub model)

Philips upper arm blood pressure monitor

(product description, nazwa /opis produktu)

to which this declaration relates is in conformity with the following harmonized standards:

(Do którego odnosi się niniejsza deklaracja jest zgodny z następującymi normami zharmonizowanymi)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Zgodnie z dyrektywami)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(oraz został wyprodukowany zgodnie ze standardami jakościowymi takimi jak ISO9001 lub CENELEC Permanent Documents)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Jednostka certyfikująca) *(Name and number/ Nazwa i numer)* *(wykonała)* *(description of intervention / rodzaj badania)*

and issued the certificate: 86443CE10 Revoked

(i wydała certyfikat) *(certificate number / numer certyfikatu)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / miasto, data)

A.Speelman, CL Compliance Manager

(signature, name and function / podpis, imię i nazwisko oraz funkcja)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Relatório No.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Ano em que a marca CE é afixada)

EU DECLARATION OF CONFORMITY

(DECLARAÇÃODE CONFORMIDADE CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nome)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address)

declare under our responsibility that the product(s) DL8760

(Declara sob a sua responsabilidade que o(s) producto(s) eléctricos)

Philips

(brand name, nome da marca)

(Type version or model, Indicar versão ou modelo)

Philips upper arm blood pressure monitor

(product description, Descrição do produto)

to which this declaration relates is in conformity with the following harmonized standards:

(Aqueles a quem esta declaração se derige, está em conformidade com as seguintes normas harmonizadas)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Na sequência do disposto em:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(E são produzidos sob um regime de qualidade, pelo menos, em conformidade com a norma ISO 9001 ou Documentos Permanentes CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(O organismo notificado) *(Name and number/ Nome e número)* *(realizada)* *(description of intervention / descrição da intervenção)*

and issued the certificate: 86443CE10 Revoked

(E emitido o certificado) *(certificate number / certificado número)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / local, data)

A.Speelman, CL Compliance Manager

(signature, name and function / assinatura, nome e função)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Nr. raport)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Anul în care este aplicat marcajul CE)

EU DECLARATION OF CONFORMITY

(DECLARAȚIE DE CONFORMITATE CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Nume)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresă)

declare under our responsibility that the product(s) DL8760

(Declarăm pe proprie răspundere că produsul (produsele) electric(e))

Philips

(brand name, marca)

(Type version or model, Tip sau model)

Philips upper arm blood pressure monitor

(product description, descriere produs)

to which this declaration relates is in conformity with the following harmonized standards:

(La care se referă această declarație, este in conformitate cu următoarele standarde armonizate)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(În conformitate cu dispozițiile directivelor)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Și sunt fabricate după o schemă de calitate conformă cel puțin cu standardul ISO 9001 sau Documentele Permanente CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Organismul notificat) *(Name and number/ Nume si număr)* *(a efectuat)* *(description of intervention / descrierea intervenției)*

and issued the certificate: 86443CE10 Revoked

(Și a emis certificatul) *(certificate number / Numărul certificatului)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / locul, data)

A.Speelman, CL Compliance Manager

(signature, name and function / semnătura, nume și funcție)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Номер протокола)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Год начала маркировки знаком CE)

EU DECLARATION OF CONFORMITY

(CE Декларация о соответствии)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Юридическое имя)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / адрес)

declare under our responsibility that the product(s): DL8760

(Декларируем под нашу ответственность, что электрическая продукция)

Philips

(brand name, торговая марка)

(Type version or model, тип, модель)

Philips upper arm blood pressure monitor

(product description, описание продукции)

to which this declaration relates is in conformity with the following harmonized standards:

(указанная в данной декларации, соответствует требованиям следующих стандартов:)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(В соответствие с положениями:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(по крайней мере, в соответствии с ISO 9001 или)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344
(Нотифицированный Орган) *(Name and number/ Название и номер)*

performed: Annex V 93/42/EEC
(проверил(а)) *(description of intervention / описание проверки)*

and issued the certificate: 86443CE10 Revoked
(и выпустил(а) сертификат) *(certificate number / номер сертификата)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / место, дата)

A.Speelman, CL Compliance Manager

(signature, name and function / подпись, имя и должность)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Správa č.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Rok v ktorom je opatrený znakom CE)

EU DECLARATION OF CONFORMITY

(Rok v ktorom je opatrený znakom CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Meno)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresa)

declare under our responsibility that the product(s) DL8760

(Prehlasujeme na svoju zodpovednosť, že elektrický výrobok(y))

Philips

(brand name, názov značky)

(Type version or model, Typové označenie alebo model)

Philips upper arm blood pressure monitor

(product description, opis prístroja)

to which this declaration relates is in conformity with the following harmonized standards:

(Na ktorý sa toto vyhlásenie vzťahuje, je v zhode s nasledujúcimi harmonizovanými normami)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(V nadväznosti na ustanovenia)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(A sú vyrobené systémom kvality minimálne v súlade s normou ISO 9001 alebo CENELEC dokumentmi)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Notifikovaný orgán) *(Name and number/ Názov a číslo)* *(vykonal)* *(description of intervention / opis zásahu)*

and issued the certificate: 86443CE10 Revoked

(A vydal osvedčenie) *(certificate number / číslo osvedčenia)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / miesto, dátum)

A.Speelman, CL Compliance Manager

(signature, name and function / podpis, meno a funkcia)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Številka poročila)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Leto namstitve CE znaka)

EU DECLARATION OF CONFORMITY

(Izjava o skladnosti)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Ime)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / Naslov)

declare under our responsibility that the product(s) DL8760

(S polno odgovornostjo izjavljamo)

Philips

(brand name, Ime znamke)

(Type version or model, Tip, verzija ali model)

Philips upper arm blood pressure monitor

(product description, Opis proizvoda)

to which this declaration relates is in conformity with the following harmonized standards:

(Na katerega se nanaša ta izjava je skladen z naslednjimi harmoniziranimi standardi)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(V skladu z naslednjimi odločbami)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(In so proizvedeni v skladu s shemo kakovosti najmanj v skladu z ISO 9001 ali CENELEC stalnimi dokumenti)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Priglašeno organ) *(Name and number/ Ime in številka)* *(Izvršeno)* *(description of intervention / Opis ukrepa)*

and issued the certificate: 86443CE10 Revoked

(Izdaja certifikat) *(certificate number / Številka certifikata)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / Kraj, datum)

A.Speelman, CL Compliance Manager

(signature, name and function / Podpis, Ime in funkcija)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Döküman Numarası)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / CE İbaresinin eklendiği yıl (yyyy/aa))

EU DECLARATION OF CONFORMITY

(EU UYGUNLUK BEYANI)

PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / İmalatçının ismi)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / İmalatçının adresi)

This declaration of conformity is issued under the sole responsibility of the manufacturer
(Bu uygunluk beyanı yalnızca imalatçının kendi sorumluluğu altında düzenlenir)

DL8760

Philips

(brand name, İsim)

(Type version or model, Tip veya model)

Philips upper arm blood pressure monitor

(product description, Ürün Açıklamas)

to which this declaration relates is in conformity with the following harmonized standards:

(aşağıda belirtilen ilgili standartların gerektirdiği uygunluğa sahip olduğunu beyan ederiz)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Yasal hükümler şu şekildedir:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(En az ISO 9001 veya CENELEC Daimi Belgelerine uygun kalite şemasına binaen mevcut ürünlerdir)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Yetkili Kurul) *(Name and number/ Isin ve numara)* *(yerine getirmiştir)* *(description of intervention /müdahalenin tanımı)*

and issued the certificate: 86443CE10 Revoked

(sertifikayı düzenlemiştir) *(certificate number / sertifika numarası)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / Yer ve tarih)

A.Speelman, CL Compliance Manager

(signature, name and function / İmza, isim ve görevi)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Broj izvještaja)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Godina ishođenja CE oznake)

EU DECLARATION OF CONFORMITY

(Izjava o sukladnosti)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Ime)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / Adresa)

declare under our responsibility that the product(s) DL8760

(Odgovorno izjavljujemo da je elektični uređaj(i))

Philips

(brand name, Naziv robne marke)

(Type version or model, Tipska oznaka ili model)

Philips upper arm blood pressure monitor

(product description, opis proizvoda)

to which this declaration relates is in conformity with the following harmonized standards:

(Na koje se ova izjava odnosi zadovoljava sljedeće usklađene norme)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Slijedom odredbi:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(najmanje u skladu sa normom ISO 9001 ili)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Nadležno tijelo) *(Name and number/ Ime i broj)* *(Izveden)* *(description of intervention / Opis intervencije)*

and issued the certificate: 86443CE10 Revoked

(I izdana je potvrda) *(certificate number / Broj potvrde)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / Mjesto ,datum)

A.Speelman, CL Compliance Manager

(signature, name and function / Potpis,ime i radno mjesto)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Αρ. έκθεσης)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Έτος επικόλλησης του σήματος συμμόρφωσης CE)

EU DECLARATION OF CONFORMITY

(ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ CE)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Επωνυμία)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / Διεύθυνση)

declare under our responsibility that the product(s) DL8760

(Δηλώνουμε υπεύθυνα ότι το ηλεκτρολογικό προϊόν/ προϊόντα)

Philips

(brand name, ονομασία μάρκας)

(Type version or model, Τύπος έκδοσης ή μοντέλο)

Philips upper arm blood pressure monitor

(product description, περιγραφή προϊόντος)

to which this declaration relates is in conformity with the following harmonized standards:

(στο οποίο/ στα οποία αφορά η παρούσα δήλωση συμμορφούται/ συμμορφούνται με τα εξής εναρμονισμένα πρότυπα)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(Σύμφωνα με τις διατάξεις των οδηγιών)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(Και παράγεται/ παράγονται σύμφωνα με ένα ποιοτικό πρόγραμμα που συμμορφούται, κατ'ελάχιστον, με το πρότυπο ISO 9001 ή με τα Μόνιμα Έγγραφα Τεκμηρίωσης της CENELEC)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Ο ειδοποιηθείς οργανισμός) *(Name and number/ Ονομασία και αριθμός)* *(διεξήγαγε)* *(description of intervention / περιγραφή παρέμβασης)*

and issued the certificate: 86443CE10 Revoked

(Και εξέδωσε το πιστοποιητικό) *(certificate number / αριθμός πιστοποιητικού)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / τόπος, ημερομηνία)

A.Speelman, CL Compliance Manager

(signature, name and function / υπογραφή, ονοματεπώνυμο και λειτουργία)

Philips Consumer Lifestyle B.V.

1914

(Document No. / Документ №)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Година на поставяне на CE маркировката)

EU DECLARATION OF CONFORMITY

(CE Декларация за съответствие)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name / Име)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / адрес)

declare under our responsibility that the product(s) DL8760

(Декларираме на наша отговорност, че електрическият(те) уред(и):

Philips

(Brand name, търговска марка)

(Type version or model, Серия или модел)

Philips upper arm blood pressure monitor

(product description, описание на продукта(ите))

to which this declaration relates is in conformity with the following harmonized standards:

(Към който(които) се отнася тази декларация е(са) в съответствие със следните установени стандарти)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(В съответствие с директиви:)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(и са произведени под система за качествен контрол най-малко в съответствие с ISO 9001 или)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Известяващата институция) *(Name and number/ Име и номер)* *(извърши)* *(description of intervention / описание на проверката)*

and issued the certificate: 86443CE10 Revoked

(И издаде сертификат) *(certificate number / номер на сертификата)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / място, дата)

A.Speelman, CL Compliance Manager

(signature, name and function / подпис, име и длъжност)

EDC EN-SER:

Philips Consumer Lifestyle B.V.

1914

(Document No. / Dokument br.)

2015/11

(Year, Month (yyyy/mm) in which the CE mark is affixed / Godina kada je dodeljena CE oznaka)

EU DECLARATION OF CONFORMITY

(EU DEKLARACIJA O USAGLAŠENOSTI)

We, PHILIPS CONSUMER LIFESTYLE B.V.

(Company name /Naziv privrednog društva)

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / adresa)

declare under our responsibility that the product(s) DL8760

(izjavljujemo pod punom odgovornošću da je(su) električni proizvod(i):)

Philips

(brand name, naziv robne marke)

(Type version or model, Verzija tipa ili model)

Philips upper arm blood pressure monitor

(product description, opis proizvoda)

to which this declaration relates is in conformity with the following harmonized standards:

(na koji se ova deklaracija odnosi u skladu sa sledećim usaglašenim standardima:)

EN 50563:2011, EN50564:2011, EN 60601-1:2006, EN 60601-1-11:2010, EN 60601-1-2:2007
EN 62304:2006
EN 60601-1-6:2010, EN 62366:2008, EN 1060-3:1997, EN 1060-4:2004
ISO 10993-1:2009, ISO 10993-5:2009
EN ISO14971:2012, EN 980:2008, EN 1041:2008
EN 300 328:2012, EN 301 489-1:2012, EN 301 489-17:2012, EN 62479:2010
EN ISO 13485:2012

following the provisions of :

(U skladu sa odredbama)

93/42/EEC
1999/5/EC
2014/30/EU
2011/65/EU
2012/19/EU, 2009/125/EC

And are produced under a quality scheme at least in conformity with ISO 9001 or CENELEC Permanent Documents

(I da su proizvedeni prema šemi kvaliteta koja je najmanje u skladu sa ISO 9001 ili CENELEC stalnom dokumentacijom)

Only for Medical Devices produced under a quality scheme at least in conformity with EN13485:

The Notified Body: DEKRA 0344 performed: Annex V 93/42/EEC

(Ovlašćeno telo) *(Name and number/ Naziv i broj)* *(izvršeno)* *(description of intervention / opis intervencije)*

and issued the certificate: 86443CE10 Revoked

(i izdat sertifikat) *(certificate number / broj sertifikata)*

Remarks: Class IIa. Device Certificate has been revoked. Device no longer commercially available. Last manufacturing date: 2017-02-08, last serial no.: BA2038170200586D

Drachten, 14-mrt-18

(place,date / potpis, ime i funkcija)

A.Speelman, CL Compliance Manager

(signature, name and function)