Philips Consumer Lifestyle B.V.

2938

(Document No.)

2022/03

(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): SCH400

Philips
(brand name)

(Type version or model)

Baby care set
(product description)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD
(Name and number)

and issued the certificate: 86443CE09
(certificate number)

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22
(place,date)

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

Philips Consumer Lifestyle B.V.

2938

(Document No. /Bericht Nr.)

2022/03

(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): SCH400

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

Philips

(brand name, Markenname)

(Type version or model, Typenbezeichnung oder Modell)

Baby care set

(product description, Produktbezeichnung)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(auf die sich diese Konformitätserklärung bezieht, allen nachstehenden harmonisierten Normen der Union entspricht:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Bezugnahme auf die folgenden harmonisierten Normen:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / Ort, Datum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Numéro du document)

2022/03

(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): SCH400

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

Philips

(brand name, nom de la marque)

(Type version or model, référence ou modèle)

Baby care set

(product description, description du produit)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(auquel cette déclaration se rapporte, est conforme à la législation d'harmonisation de l'Union suivante :)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Et fait référence aux normes harmonisées suivantes :)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / lieu, date)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Documentnummer)

2022/03

(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): SCH400

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

Philips

(brand name, merknaam)

(Type version or model, typenummer of model)

Baby care set

(product description, productbeschrijving)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(waarop deze verklaring betrekking heeft in overeenstemming is met de volgende harmonisatiewetten van de Europese Unie:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Onder verwijzing naar de volgende geharmoniseerde normen:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / plaats, datum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Číslo zprávy)

2022/03

(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): SCH400

(Prohlašujeme na svou odpovědnost, že elektrický výrobek)

Philips

(brand name, značka)

(Type version or model, Typ verze nebo model)

Baby care set

(product description, popis výrobku)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(ke kterému se toto prohlášení vztahuje, je v souladu s následujícími harmonizačními právními předpisy EU:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Odkazující na následovné harmonizované normy:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / místo, datum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Rapportnummer)

2022/03

(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): SCH400

(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)

Baby care set

(product description, produktbeskrivelse)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(til hvilke(t) denne erklæring relaterer sig, er i overensstemmelse med følgende EUharmoniseringslovgivning:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Med reference til følgende harmoniserede standarder:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / sted, dato)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Documento nº.)

2022/03

(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): SCH400

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

Philips

(brand name, nombre de la marca)

(Type version or model, Referencia o modelo)

Baby care set

(product description, descripción del producto)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(al que hace referencia esta declaración cumple la siguiente legislación sobre armonización de la Unión:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(En referencia a las siguientes normas armonizadas:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / lugar, fecha)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Raportti nr.)

2022/03

(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): SCH400

(Ilmoitus seuraavista vastuullamme olevista sähkötuotteista:)

Philips

(brand name, Brändinimi)

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

Baby care set

(product description, Tuotekuvaus)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(Tämä vakuutus on yhdenmukainen seuraavan Euroopan unionin yhdenmukaistamislainsäädännön kanssa:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Viitaten seuraaviin yhdenmukaistettuihin standardeihin:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / paikka, päiväys)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Jelentés száma)

2022/03

(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): SCH400

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

Philips

(brand name, márkanév)

(Type version or model, Típusváltozat vagy modell)

Baby care set

(product description, termék megnevezése)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(amelyre ez nyilatkozat vonatkozik, megfelel a következő uniós harmonizációs jogszabályoknak:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Hivatkozva a következő harmonizált szabványokra:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / hely, dátum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Report Numero)

2022/03

(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): SCH400

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

Philips

(brand name, marchio)

(Type version or model, modello o versione)

Baby care set

(product description, descrizione del prodotto)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(al quale la presente dichiarazione si riferisce è conforme alla seguente normativa di armonizzazione dell'Unione:

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(In riferimento alle seguenti norme tecniche armonizzate:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / luogo e data)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Pranešimo Nr.)

2022/03

(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): SCH400

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

Philips

(brand name, firmos ženklo pavadinimas)

(Type version or model, Tipas arba modelis)

Baby care set

(product description, gaminio aprašymas)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(šiai deklaracijai, sutinkamai su toliau nurodytais jungtiniais harmonizacijos reglamentais:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Sutinkamai su šiais harmonizuotais standartais:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / vieta, data)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Ziņojums Nr)

2022/03

(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): SCH400

(deklarēt zem vai atbildība ka, elektronisks produkts)

Philips

(brand name, fabrikas marka vārds)

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

Baby care set

(product description, produkta apraksts)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(uz ko attiecas šī deklarācija, atbilst tālāk minētajiem Eiropas Savienības saskaņošanas tiesību aktiem:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Atsaucas uz tālāk minētajiem saskaņotajiem standartiem:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / vieta, datums)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Numer raportu)

2022/03

(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): SCH400

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

Philips

(brand name, marka)

(Type version or model, Typ lub model)

Baby care set

(product description, nazwa /opis produktu)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(do którego odnosi się niniejsza deklaracja jest zgodne z następującymi normami zharmonizowanymi:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Odwołującymi się do następujących norm zharmonizowanych:

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / miasto, data)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Relatório No.)

2022/03

(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): SCH400

(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)

Baby care set

(product description, Descrição do produto)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(a que esta declaração se refere está em conformidade com a seguinte legislação de harmonização da União:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Com referência aos seguintes padrões de harmonização:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / local, data)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Nr. raport)

2022/03

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

EU DECLARATION OF CONFORMITY

(DECLARAŢIE 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): SCH400

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

Philips

(brand name, marca)

(Type version or model, Tip sau model)

Baby care set

(product description, descriere produs)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(la care se referă prezenta declarație este în conformitate cu următoarea legislație de armonizare a Uniunii:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Se referă la următoarele standarde armonizate:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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

(Şi sunt fabricate după o schemă de calitate conformă cel puţin 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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / locul, data)

A.Speelman, CL Compliance Manager

(signature, name and function / semnătura, nume şi funcţie)

Philips Consumer Lifestyle B.V.

2938

(Document No. / Номер протокола)

2022/03

(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): SCH400

(Декларируем под нашу ответственность, что электрическая продукция)

Philips

(brand name, торговая марка)

(Type version or model, тип, модель)

Baby care set

(product description, описание продукции)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(к которому относится данное заявление, соответствует следующим законодательным актам Европейского Союза о гармонизации технических нормативов:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Эти нормативы касаются следующих гармонизированных стандартов:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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 performed: MDD

(Нотифицированный Орган) *(Name and number/ Название и номер)* *(проверил(а))* *(description of intervention / описание проверки)*

and issued the certificate: 86443CE09

(и выпустил(а) сертификат) *(certificate number / номер сертификата)*

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / место, дата)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Správa č.)

2022/03

(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): SCH400

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

Philips

(brand name, názov značky)

(Type version or model, Typové označenie alebo model)

Baby care set

(product description, opis prístroja)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(na ktorý sa toto vyhlásenie vzťahuje, je v súlade s nasledujúcimi harmonizovanými právnymi predpismi Európskej únie:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(S odvolaním sa na nasledujúce harmonizované normy:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / miesto, dátum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Številka poročila)

2022/03

(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): SCH400

(S polno odgovornostjo izjavljamo)

Philips

(brand name, Ime znamke)

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

Baby care set

(product description, Opis proizvoda)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(na katerega se nanaša ta izjava, je skladen z naslednjo usklajevalno zakonodajo Unije:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(S sklicevanjem na naslednje usklajene standarde:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / Kraj, datum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Döküman Numarası)

2022/03

(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)

SCH400

(Type version or model, Tip veya model)

Philips

(brand name, İsim)

Baby care set

(product description, Ürün Açıklamas)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

((bu beyanın ilgili olduğu) aşağıdaki Union uyumlaştırma mevzuatına uygundur:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Aşağıdaki uyumlaştırılmış standartlara atıfta bulunmaktadır:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / Yer ve tarih)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Broj izvještaja)

2022/03

(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): SCH400

(Odgovorno izjavljujemo da je elektični uređaj(i))

Philips

(brand name, Naziv robne marke)

(Type version or model, Tipska oznaka ili model)

Baby care set

(product description, opis proizvoda)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(na koji se odnosi ova deklaracija u skladu je sa sljedećim zakonima o harmonizaciji Unije:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Odnosi se na sljedeće norme za harmonizaciju:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / Mjesto ,datum)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Αρ. έκθεσης)

2022/03

(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): SCH400

(Δηλώνουμε υπεύθυνα ότι το ηλεκτρολογικό προϊόν/ προϊόντα)

Philips

(brand name, ονομασία μάρκας)

(Type version or model, Τύπος έκδοσης ή μοντέλο)

Baby care set

(product description, περιγραφή προϊόντος)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(στο οποίο αναφέρεται αυτή η δήλωση συμμορφώνεται με την παρακάτω νομοθεσία εναρμόνισης της Ένωσης:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Αναφορικά με τα παρακάτω εναρμονισμένα πρότυπα:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / τόπος, ημερομηνία)

A.Speelman, CL Compliance Manager

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

Philips Consumer Lifestyle B.V.

2938

(Document No. / Документ №)

2022/03

(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): SCH400

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

Philips

(Brand name, търговска марка)

(Type version or model, Серия или модел)

Baby care set

(product description, описание на продукта(ите))

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(към който се отнася настоящата декларация, е в съответствие със следното законодателство на Съюза относно хармонизацията:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Отнася се към следните хармонизирани стандарти:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(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.

2938

(Document No. / Dokument br.)

2022/03

(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): SCH400

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

Philips

(brand name, naziv robne marke)

(Type version or model, Verzija tipa ili model)

Baby care set

(product description, opis proizvoda)

to which this declaration relates is in compliance with the following Union harmonisation legislation:

(na koje se ova izjava odnosi usklađeni su sa sledećim propisima za harmonizaciju u Uniji:)

93/42/EEC
2011/65/EU

Referring to the following harmonised standards:

(Odnosi se na sledeće harmonizovane standarde:)

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008, EN 60601-1-11:2015
ISO 80601-2-56:2009
EN ISO 14971:2012
EN 12470-3:2000 + A1:2009
EN ISO 10993-1:2009 +AC2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010
EN 62304:2006 + AMD1:2015
EN ISO 13485:2016
EN 1041:2008, EN 15223-1:2016
EN 50581:2012

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: MDD

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

and issued the certificate: 86443CE09

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

Remarks: The thermometer is a Class IIa medical device in Europe, according to Rule 10, Annex V and VII of the MDD – Active devices for diagnosis

Drachten, 29-Mar-22

(place,date / potpis, ime i funkcija)

A.Speelman, CL Compliance Manager

(signature, name and function)