

## 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): SCF338

Philips Avent

(brand name)

(Type version or model)

Double Breast pump kit

(product description)

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

93/42/EC

Referring to the following harmonised standards or other technical specifications:

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Name and number)

performed: MDD Annex V/VII

and issued the certificate: 86443CE12

(certificate number)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date)

A.Speelman, CL Compliance Manager

(signature, name and function)

3265

2021/02

(Document No. /Bericht Nr. )

(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): SCF338

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

Philips Avent

(brand name, Markenname)

(Type version or model, Typenbezeichnung oder Modell )

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Bezugnahme auf die folgenden harmonisierten Normen oder anderen technischen Spezifikationen:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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

(und die gemäß eines Qualitätssystems 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 Cert. BV CE0344

(benannte Stelle)

(Name and number/ Name und Kennnummer )

performed: MDD Annex V/VII

(ausgeführt)

(description of intervention / Beschreibung des Verfahrens)

and issued the certificate: 86443CE12

(und stellen das Zertifikat)

(certificate number / Zertifikatnummer)

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / Ort, Datum )

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Numéro du document)

(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): SCF338

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

Philips Avent

(brand name, nom de la marque)

(Type version or model, référence ou modèle)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Et fait référence aux normes harmonisées ou autres prescriptions techniques suivantes:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

performed: MDD Annex V/VII

(L'Organisme Notifié) (Name and number/ nom et numéro)

(a effectué) (description of intervention / description de l'intervention)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / lieu, date)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Documentnummer)

(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): SCF338

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

Philips Avent

(brand name, merknaam)

(Type version or model, typenummer of model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Onder verwijzing naar de volgende geharmoniseerde normen of andere technische specificaties:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Notified Body)

(Name and number/ Naam en nummer)

performed: MDD Annex V/VII

(heeft uitgevoerd) (description of intervention / uitgevoerd testprotocol)

and issued the certificate: 86443CE12

(en heeft een certificaat uitgegeven)

(certificate number / nummer van het certificaat)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / plaats, datum)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Číslo zprávy)

(Year, Month (yyyy/mm) in which the CE mark is affixed / Rok udělení 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): SCF338

(Prohlašujeme na svou odpovědnost, že elektrický výrobek)

Philips Avent

(brand name, značka)

(Type version or model, Typ verze nebo model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Odkazující na následovně harmonizované normy nebo další technické specifikace:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Kompetentní orgán)

(Name and number/ Název a číslo)

performed: MDD Annex V/VII

(provedl)

(description of intervention / popis operace)

and issued the certificate: 86443CE12

(a vydal certifikát,)

(certificate number / číslo certifikátu)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / místo, datum)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Rapportnummer)

(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): SCF338

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

Philips Avent

(brand name, navn på varemærke)

(Type version or model, type eller model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Med reference til følgende harmoniserede standarder eller andre tekniske specifikationer:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Det Notificerede Organ) (Name and number/ Navn og nummer)

performed: MDD Annex V/VII

(har gennemført) (description of intervention / beskrivelse af intervention)

and issued the certificate: 86443CE12

(og udstedt erklæringen) (certificate number / erklæringsnummer)

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / sted, dato)

A. Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Documento nº.)

(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 compañía )

TUSSENDIEPEN 4, 9206 AD DRACHTEN, THE NETHERLANDS

(address / dirección )

declare under our responsibility that the product(s): SCF338

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

Philips Avent

(brand name, nombre de la marca)

(Type version or model, Referencia o modelo)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(En referencia a las siguientes normas armonizadas u otras especificaciones técnicas:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

performed: MDD Annex V/VII

(El organismo notificado) (Name and number/ Nombre y número)

(realizador) (description of intervention / descripción de la intervención)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / lugar, fecha)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Raportti nr.)

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

## 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): SCF338

(Ilmoitus seuraavista vastuullamme olevista sähkötuotteista:)

Philips Avent

(brand name, Brändinimi)

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

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Viitaten seuraaviin yhdenmukaistettuihin standardeihin tai muihin teknisiin tietoihin:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Ilmoitettu laitos)

(Name and number/ Nimi ja numero)

performed: MDD Annex V/VII

(suoritetaan)

(description of intervention / toimenpiteen kuvaus)

and issued the certificate: 86443CE12

(Todistuksen antaja)

(certificate number / Sertifikaatin numero)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / paikka, päiväs)

A.Speelman, CL Compliance Manager

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



3265

2021/02

(Document No. / Jelentés száma)

(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): SCF338

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

Philips Avent

(brand name, márkanev)

(Type version or model, Típusváltozat vagy modell)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Hivatkozva a következő harmonizált szabványokra vagy más műszaki előírásokra:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Bejelentett testület)

(Name and number/ Név és szám)

performed: MDD Annex V/VII

(teljesítve)

(description of intervention / intézkedés leírása)

and issued the certificate: 86443CE12

(és a kibocsátott tanúsítvány)

(certificate number / tanúsítvány száma)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / hely, dátum)

A. Speelman, CL Compliance Manager

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

# 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): SCF338

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

Philips Avent

(brand name, marchio)

(Type version or model, modello o versione )

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(In riferimento alle seguenti norme tecniche armonizzate o ad altre specifiche tecniche:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

performed: MDD Annex V/VII

(L'ente certificatore notificato) (Name and number/ denominazione e numero)

(ha eseguito) (description of intervention / descrizione dell'intervento )

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / luogo e data)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Pranešimo Nr.)

(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): SCF338

(Deklaruojame, kad elektronikos gaminy (iai):)

Philips Avent

(brand name, firmos ženklo pavadinimas)

(Type version or model, Tipas arba modelis)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Sutinkamai su šiais harmonizuotais standartais arba kitomis techninėmis specifikacijomis:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Informuota įstaiga)

(Name and number/ Pavadinimas ir numeris)

performed: MDD Annex V/VII

(atlikta)

(description of intervention / intervencijos aprašymas)

and issued the certificate: 86443CE12

(Sertifikatas išleistas)

(certificate number / sertifikato numeris)

Remarks: Class IIa rule 4



Drachten, 07-Jun-23

(place, date / vieta, data)

A. Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Ziņojums Nr)

(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): SCF338

(deklarēt zem vai atbildība ka, elektronisks produkts)

Philips Avent

(brand name, fabrikas marka vārds)

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

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Atsaucas uz tālāk minētajiem saskaņotajiem standartiem vai citām tehniskajām specifikācijām:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Reģistrēta galvenā daļa) (Name and number/ vārds un numurs)

performed: MDD Annex V/VII

(paveikts) (description of intervention / intervencijas apraksts)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / vieta, datums)

A.Speelman, CL Compliance Manager

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

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2021/02

(Document No. / Numer raportu)

(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): SCF338

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

Philips Avent

(brand name, marka)

(Type version or model, Typ lub model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Odwołujące się do następujących norm zharmonizowanych lub innych specyfikacji technicznych:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Jednostka certyfikująca) (Name and number/ Nazwa i numer)

performed: MDD Annex V/VII

(wykonała) (description of intervention / rodzaj badania)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / miasto, data)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Relatório No.)

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

## EU DECLARATION OF CONFORMITY

(DECLARAÇÃO DE 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): SCF338

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

Philips Avent

(brand name, nome da marca)

(Type version or model, Indicar versão ou modelo)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Com referência aos seguintes padrões de harmonização ou outras especificações técnicas:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(O organismo notificado) (Name and number/ Nome e número)

performed: MDD Annex V/VII

(realizada) (description of intervention / descrição da intervenção)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / local, data)

A. Speelman, CL Compliance Manager

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

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2021/02

(Document No. / Nr. raport)

(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): SCF338

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

Philips Avent

(brand name, marca)

(Type version or model, Tip sau model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Se referă la următoarele standarde armonizate sau alte specificații tehnice:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Organismul notificat) (Name and number/ Nume și număr)

performed: MDD Annex V/VII

(a efectuat) (description of intervention / descrierea intervenției)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / locul, data)

A.Speelman, CL Compliance Manager

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

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2021/02

(Document No. / Номер протокола)

(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): SCF338

(Декларируем под нашу ответственность, что электрическая продукция)

Philips Avent

(brand name, торговая марка)

(Type version or model, тип, модель)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Эти нормативы касаются следующих гармонизированных стандартов и прочих технических спецификаций:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Нотифицированный Орган) (Name and number/ Название и номер)

performed: MDD Annex V/VII

(проверил(а)) (description of intervention / описание проверки)

and issued the certificate: 86443CE12

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

сертификат)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / место, дата)

A.Speelman, CL Compliance Manager

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



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2021/02

(Document No. / Správa č.)

(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): SCF338

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

Philips Avent

(brand name, názov značky)

(Type version or model, Typové označenie alebo model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(S odvolaním sa na nasledujúce harmonizované normy alebo iné technické špecifikácie:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Notifikovaný orgán) (Name and number/ Názov a číslo)

performed: MDD Annex V/VII

(vykonal) (description of intervention / opis zásahu)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / miesto, dátum)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Številka poročila)

(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): SCF338

(S polno odgovornostjo izjavljamo)

Philips Avent

(brand name, Ime znamke)

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

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(S sklicevanjem na naslednje usklajene standarde ali druge tehnične specifikacije:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Priglašeno organ)

(Name and number/ Ime in številka)

performed: MDD Annex V/VII

(Izvršeno)

(description of intervention / Opis ukrepa)

and issued the certificate: 86443CE12

(Izdaja certifikat)

(certificate number / Številka certifikata)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / Kraj, datum)

A.Speelman, CL Compliance Manager

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

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2021/02

(Document No. / Döküman Numarası)

(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 SCF338

(Bu uygunluk beyanı yalnızca imalatçının kendi sorumluluğu altında düzenlenir)

Philips Avent

(brand name, İsim )

(Type version or model, Tip veya model)

Double Breast pump kit

(product description, Ürün Açıklaması )

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/EC

Referring to the following harmonised standards or other technical specifications:

(Aşağıdaki uyumlaştırılmış standartlara veya diğer teknik özelliklere atıfta bulunmaktadır:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Yetkili Kurul)

(Name and number/ İsim ve numara)

performed: MDD Annex V/VII

(yerine getirmiştir)

(description of intervention /müdahalenin tanımı )

and issued the certificate: 86443CE12

(sertifikayı düzenlemiştir)

(certificate number / sertifika numarası)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / Yer ve tarih )

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Broj izvještaja)

(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): SCF338

(Odgovorno izjavljujemo da je električni uređaj(i))

Philips Avent

(brand name, Naziv robne marke)

(Type version or model, Tipska oznaka ili model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Odnosi se na sljedeće norme za harmonizaciju ili druge tehničke podatke:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Nadležno tijelo) (Name and number/ Ime i broj)

performed: MDD Annex V/VII

(Izveden) (description of intervention / Opis intervencije)

and issued the certificate: 86443CE12

(Izdana je potvrda) (certificate number / Broj potvrde)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / Mjesto, datum)

A. Speelman, CL Compliance Manager

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

## 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): SCF338

(Δηλώνουμε υπεύθυνα ότι το ηλεκτρολογικό προϊόν/ προϊόντα)

Philips Avent

(brand name, ονομασία μάρκας)

(Type version or model, Τύπος έκδοσης ή μοντέλο)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Αναφορικά με τα παρακάτω εναρμονισμένα πρότυπα ή με άλλες τεχνικές προδιαγραφές:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

performed: MDD Annex V/VII

(Ο ειδοποιηθείς οργανισμός) (Name and number/ Ονομασία και αριθμός)

(διεξήγαγε)

(description of intervention / περιγραφή παρέμβασης)

and issued the certificate: 86443CE12

(Και εξέδωσε το πιστοποιητικό)

(certificate number / αριθμός πιστοποιητικού)

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / τόπος, ημερομηνία)

A.Speelman, CL Compliance Manager

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

3265

2021/02

(Document No. / Документ №)

(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): SCF338

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

Philips Avent

(Brand name, търговска марка)

(Type version or model, Серия или модел)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Като се позовава на следните хармонизирани стандарти или други технически спецификации:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Известяващата институция) (Name and number/ Име и номер)

performed: MDD Annex V/VII

(извърши) (description of intervention / описание на проверката)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / място, дата)

A.Speelman, CL Compliance Manager

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

**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): SCF338

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

Philips Avent

(brand name, naziv robne marke )

(Type version or model, Verzija tipa ili model)

Double Breast pump kit

(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/EC

Referring to the following harmonised standards or other technical specifications:

(Odnosi se na sledeće harmonizovane standarde ili druge tehničke specifikacije:)

EN 62366:2008 + A1:2015  
EN 62366-1:2015 + A1:2020  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2016  
EN 1041:2008 + A1:2013  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 10993-18:2009

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 Cert. BV CE0344

(Ovlašćeno telo) (Name and number/ Naziv i broj)

performed: MDD Annex V/VII

(izvršeno) (description of intervention / opis intervencije)

and issued the certificate: 86443CE12

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

Remarks: Class IIa rule 4

Drachten, 07-Jun-23

(place, date / potpis, ime i funkcija)

A. Speelman, CL Compliance Manager

(signature, name and function)