

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374

Philips

(brand name)

(Type version or model)

Electric Breast Pump

(product description)

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

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule 12

and issued the certificate: 2278024CE01

(certificate number)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place,date)

A.Speedman, CL Compliance Manager

(signature, name and function)

3480

(Document No. /Bericht Nr.)

2025/02

(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): SCF391, SCF392, SCF393, SCF394,SCF338, SCF371, SCF372, SCF373,
erklären als Verantwortliche, daß folgende(s) elektrische(n) Produkt(e) SCF374

Philips

(brand name, Markenname)

(Type version or model, Typenbezeichnung oder Modell)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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	performed:	MDR Annex IX, Class IIa Rule
(benannte Stelle)	(Name and number/ Name und Kennnummer)	(ausgeführt)	(description of intervention / Beschreibung des Verfahrens)
and issued the certificate:	2278024CE01		SRN: NL-MF-000001693
(und stellen das Zertifikat)	(certificate number / Zertifikatnummer)		
Risk Class: Class IIa		Basic UDI-DI:	08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / Ort, Datum)

A.Speelman, CL Compliance Manager

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

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
(déclarons sous notre propre responsabilité que le(s) produit(s)) SCF374

Philips

(brand name, nom de la marque)

(Type version or model, référence ou modèle)

Electric Breast Pump

(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 :)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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

(L'Organisme Notifié)

(Name and number/ nom et numéro)

performed: MDR Annex IX, Class IIa Rule

(a effectué)

(description of intervention / description de l'intervention)

and issued the certificate: 2278024CE01

(et a délivré le certificat)

(certificate number / numéro du certificat)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / lieu, date)

A.Speedman, CL Compliance Manager

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

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
(verklaren dat onder onze verantwoordelijkheid de product(en)) SCF374

Philips

(brand name, merknaam)

(Type version or model, typenummer of model)

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule
(heeft uitgevoerd) (description of intervention / uitgevoerd testprotocol)

and issued the certificate: 2278024CE01
(en heeft een certificaat uitgegeven) (certificate number / nummer van het certificaat)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / plaats, datum)

A.Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374

(Prohlašujeme na svou odpovědnost, že elektrický výrobek)

Philips

(brand name, značka)

(Type version or model, Typ verze nebo model)

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021

EN 60601-1-2:2015 + A1:2021, EN 60601-1-6:2010 + A1:2015+A2:2021

EN 62366-1:2015 + A1:2020, EN 60601-1-11:2015 + A1:2021

EN ISO 14971:2019 + A11:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009

EN ISO 10993-10:2023, EN ISO 10993-23:2021

EN ISO 10993-18:2020+A1:2023

EN ISO 10079-1:2022, EN ISO 10079-4:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

EN ISO 15223-1:2021, EN ISO 20417:2022

EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(provedl)

(description of intervention / popis operace)

and issued the certificate: 2278024CE01

(a vydal certifikát,)

(certificate number / číslo certifikátu)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / místo, datum)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(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)

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021

EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021

EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021

EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009

EN ISO 10993-10:2023, EN ISO 10993-23:2021

EN ISO 10993-18:2020+A1:2023

EN ISO 10079-1:2022, EN ISO 10079-4:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

EN ISO 15223-1:2021, EN ISO 20417:2022

EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

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

and issued the certificate: 2278024CE01

(og udstedt erklæringen)

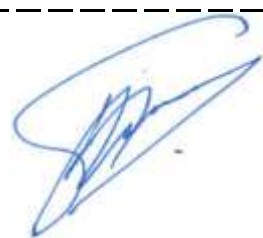
(certificate number / erklæringsnummer)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:



Drachten, 18-Feb-25

(place, date / sted, dato)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(Document No. / Documento n°.)

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(Declaramos bajo nuestra propia responsabilidad que el (los) producto(s):

Philips

(brand name, nombre de la marca)

(Type version or model, Referencia o modelo)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule
(El organismo notificado) (Name and number/ Nombre y número) (realizador) (description of intervention / descripción de la intervención)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(Y expidió el certificado) (certificate number / número de certificado)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / lugar, fecha)

A.Speedman, CL Compliance Manager
(signature, name and function / firma, nombre y cargo)

3480

2025/02

(Document No. / Raportti nr.)

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374

(Ilmoitus seuraavista vastuullamme olevista sähkötuotteista:)

Philips

(brand name, Brändinimi)

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

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

(Viitaten seuraaviin yhdenmukaistettuihin standardeihin tai muihin teknisiin tietoihin:)

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021

EN 60601-1-2:2015 + A1:2021, EN 60601-1-6:2010 + A1:2015+A2:2021

EN 62366-1:2015 + A1:2020, EN 60601-1-11:2015 + A1:2021

EN ISO 14971:2019 + A11:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009

EN ISO 10993-10:2023, EN ISO 10993-23:2021

EN ISO 10993-18:2020+A1:2023

EN ISO 10079-1:2022, EN ISO 10079-4:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

EN ISO 15223-1:2021, EN ISO 20417:2022

EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(suoritetaan) (description of intervention / toimenpiteen kuvaus)

and issued the certificate: 2278024CE01

(Todistuksen antaja)

(certificate number / Sertifikaatin numero)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / paikka, päiväys)

A.Speelman, CL Compliance Manager

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

3480

2025/02

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

SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
SCF374

Philips

(brand name, márkanév)

(Type version or model, Típusváltozat vagy modell)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule
(teljesítve) (description of intervention / intézkedés leírása)

and issued the certificate: 2278024CE01
(és a kibocsátott tanúsítvány) (certificate number / tanúsítvány száma)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / hely, dátum)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(Document No. / Report Numero)

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
SCF374
(dichiara sotto la propria responsabilità che il /i Prodotto /i elettrico/i)

Philips

(brand name, marchio)

(Type version or model, modello o versione)

Electric Breast Pump

(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:

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule
(L'ente certificatore notificato) (Name and number/ denominazione e numero) (ha eseguito) (description of intervention / descrizione dell'intervento)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(ed emesso il certificato) (certificate number / numero del certificato)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / luogo e data)

A.Speelman, CL Compliance Manager
(signature, name and function / firma , nome e funzione)

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374

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

Philips

(brand name, firmos ženklo pavadinimas)

(Type version or model, Tipas arba modelis)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(atlikta)

(description of intervention / intervencijos aprašymas)

and issued the certificate: 2278024CE01

(Sertifikatas išleistas)

(certificate number / sertifikato numeris)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / vieta, data)

A.Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(deklarēt zem vai atbildība ka, elektronisks produkts)

Philips

(brand name, fabrikas marka vārds)

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

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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 performed: MDR Annex IX, Class IIa Rule
(Reģistrēta galvenā daļa) (Name and number/ vārds un numurs) (paveikts) (description of intervention / intervencijas apraksts)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(Un izveido sertifikātu) (certificate number / sertifikāta numurs)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / vieta, datums)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
(Deklarujemy na naszą odpowiedzialność, że urządzeni(e/a) elektryczne) SCF374

Philips

(brand name, marka)

(Type version or model, Typ lub model)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(wykonała) (description of intervention / rodzaj badania)

and issued the certificate: 2278024CE01

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

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / miasto, data)

A.Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
(Declara sob a sua responsabilidade que o(s) produto(s) eléctricos) SCF374

Philips

(brand name, nome da marca)

(Type version or model, Indicar versão ou modelo)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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 performed: MDR Annex IX, Class IIa Rul
(O organismo notificado) (Name and number/ Nome e número) (realizada) (description of intervention / descrição da intervenção)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(E emitido o certificado) (certificate number / certificado número)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / local, data)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(Declarăm pe proprie răspundere că produsul (produsele) electric(e))

Philips

(brand name, marca)

(Type version or model, Tip sau model)

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021

EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021

EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021

EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009

EN ISO 10993-10:2023, EN ISO 10993-23:2021

EN ISO 10993-18:2020+A1:2023

EN ISO 10079-1:2022, EN ISO 10079-4:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

EN ISO 15223-1:2021, EN ISO 20417:2022

EN 14350:2020, EN IEC 63000:2018

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 si număr)

performed: MDR Annex IX, Class IIa Rule

(a efectuat)

(description of intervention / descrierea intervenției)

and issued the certificate: 2278024CE01

(Și a emis certificatul)

(certificate number / Numărul certificatului)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / locul, data)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(Декларируем под нашу ответственность, что электрическая продукция)

Philips

(brand name, торговая марка)

(Type version or model, тип, модель)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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 performed: MDR Annex IX, Class IIa Rule
(Нотифицированный Орган) (Name and number/ Название и номер) (проверил(а)) (description of intervention / описание проверки)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(и выпустил(а) сертификат) (certificate number / номер сертификата)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / место, дата)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(Prehlasujeme na svoju zodpovednosť, že elektrický výrobok(y))

Philips

(brand name, názov značky)

(Type version or model, Typové označenie alebo model)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(vykonan)

(description of intervention / opis zásahu)

and issued the certificate: 2278024CE01

(A vydal osvedčenie)

(certificate number / číslo osvedčenia)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / miesto, dátum)

A.Speelman, CL Compliance Manager

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

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(S polno odgovornostjo izjavljamo)

Philips

(brand name, Ime znamke)

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

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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 performed: MDR Annex IX, Class IIa Rule
(Priglašeno organ) (Name and number/ Ime in številka) (Izvršeno) (description of intervention / Opis ukrepa)

and issued the certificate: 2278024CE01 SRN: NL-MF-000001693
(Izdaja certifikat) (certificate number / Številka certifikata)

Risk Class: Class IIa Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place,date / Kraj, datum)

A.Speelman, CL Compliance Manager
(signature, name and function / Podpis, Ime in funkcija)

3480

(Document No. / Döküman Numarası)

2025/02

(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

SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
SCF374

(Bu uygunluk beyanı yalnızca imalatçının kendi sorumluluğu altında
düzenlenir)

Philips

(Type version or model, Tip veya model)

(brand name, İsim)

Electric Breast Pump

(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:)

(EU) 2017/745

(EU) 10/2011

(EU) 2023/1542

2006/42/EC

2012/19/EU

2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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/ Isin ve numara)

performed: MDR Annex IX, Class IIa Rule

(yerine getirmiştir) (description of intervention /müdahalenin tanımı)

and issued the certificate: 2278024CE01

(sertifikayı düzenlemiştir)

(certificate number / sertifika numarası)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place,date / Yer ve tarih)

A.Speelman, CL Compliance Manager

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

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
SCF374
(Odgovorno izjavljujemo da je električni uređaj(i))

Philips

(brand name, Naziv robne marke)

(Type version or model, Tipska oznaka ili model)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(Izveden)

(description of intervention / Opis intervencije)

and issued the certificate: 2278024CE01

(I izdana je potvrda)

(certificate number / Broj potvrde)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / Mjesto, datum)

A. Speelman, CL Compliance Manager

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

3480

2025/02

(Document No. / Αρ. έκθεσης)

(Year, Month (yyyy/mm) in which the CE mark is affixed / Έτος επικύρωσης 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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374

(Δηλώνουμε υπεύθυνα ότι το ηλεκτρολογικό προϊόν/ προϊόντα)

Philips

(brand name, ονομασία μάρκας)

(Type version or model, Τύπος έκδοσης ή μοντέλο)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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

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

performed: MDR Annex IX, Class IIa Rule

(διεξήγαγε) (description of intervention / περιγραφή παρέμβασης)

and issued the certificate: 2278024CE01

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

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / τόπος, ημερομηνία)

A.Speelman, CL Compliance Manager

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

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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373,
(Декларираме на наша отговорност, че електрическият(те) уред(и): SCF374

Philips

(Brand name, търговска марка)

(Type version or model, Серия или модел)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

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

and issued the certificate: 2278024CE01

(И издаде сертификата)

(certificate number / номер на сертификата)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place, date / място, дата)

A.Speelman, CL Compliance Manager

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

3480

2025/02

(Document No. / Dokument br.)

(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): SCF391, SCF392, SCF393, SCF394, SCF338, SCF371, SCF372, SCF373, SCF374
(izjavljujemo pod punom odgovornošću da je(su) električni proizvod(i):)

Philips

(brand name, naziv robne marke)

(Type version or model, Verzija tipa ili model)

Electric Breast Pump

(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:)

(EU) 2017/745
(EU) 10/2011
(EU) 2023/1542
2006/42/EC
2012/19/EU
2011/65/EU

Referring to the following harmonised standards or other technical specifications:

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

EN 60601-1:2006 + A1:2013+A11:2013+A12:2014+A2:2021
EN 60601-1-2:2015 + A1:2021 , EN 60601-1-6:2010 + A1:2015+A2:2021
EN 62366-1:2015 + A1:2020 , EN 60601-1-11:2015 + A1:2021
EN ISO 14971:2019 + A11:2021 , EN ISO 10993-1:2020, EN ISO 10993-5:2009
EN ISO 10993-10:2023, EN ISO 10993-23:2021
EN ISO 10993-18:2020+A1:2023
EN ISO 10079-1:2022, EN ISO 10079-4:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 15223-1:2021, EN ISO 20417:2022
EN 14350:2020, EN IEC 63000:2018

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: MDR Annex IX, Class IIa Rule

(izvršeno)

(description of intervention / opis intervencije)

and issued the certificate: 2278024CE01

(i izdat sertifikata)

(certificate number / broj sertifikata)

SRN: NL-MF-000001693

Risk Class: Class IIa

Basic UDI-DI: 08710103BM781JY

Remarks:

Drachten, 18-Feb-25

(place,date / potpis, ime i funkcija)

A.Speelman, CL Compliance Manager

(signature, name and function)