

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): SCF157

Philips

(brand name)

(Type version or model)

Comfort Breast Shell

(product description)

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

(EU) 2017/745

Referring to the following harmonised standards or other technical specifications:

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Name and number)

performed: Class I Rule 1

and issued the certificate:

(certificate number)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date)

A.Speelman, CL Compliance Manager

(signature, name and function)

3628

(Document No. /Bericht Nr.)

07/2011

(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): SCF157

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

Philips

(brand name, Markenname)

(Type version or model, Typenbezeichnung oder Modell)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(benannte Stelle)

(Name and number/ Name und Kennnummer)

performed: Class I Rule 1

(ausgeführt)

(description of intervention / Beschreibung des Verfahrens)

and issued the certificate:

(und stellen das Zertifikat)

(certificate number / Zertifikatnummer)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:



Drachten, 19-Jun-25

(place, date / Ort, Datum)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, nom de la marque)

(Type version or model, référence ou modèle)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(L'Organisme Notifié)

(Name and number/ nom et numéro)

performed: Class I Rule 1

(a effectué)

(description of intervention / description de l'intervention)

and issued the certificate:

(et a délivré le certificat)

(certificate number / numéro du certificat)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:



Drachten, 19-Jun-25

(place, date / lieu, date)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, merknaam)

(Type version or model, typenummer of model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Notified Body)

(Name and number/ Naam en nummer)

performed: Class I Rule 1

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

and issued the certificate:

(en heeft een certificaat uitgegeven)

(certificate number / nummer van het certificaat)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / plaats, datum)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(Prohlašujeme na svou odpovědnost, že elektrický výrobek)

Philips

(brand name, značka)

(Type version or model, Typ verze nebo model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Kompetentní orgán)

(Name and number/ Název a číslo)

performed: Class I Rule 1

(provedl)

(description of intervention / popis operace)

and issued the certificate:

(a vydal certifikát,)

(certificate number / číslo certifikátu)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:



Drachten, 19-Jun-25

(place, date / místo, datum)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(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)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Det Notificerede Organ)

(Name and number/ Navn og nummer)

performed: Class I Rule 1

(har gennemført)

(description of intervention / beskrivelse af intervention)

and issued the certificate:

(og udstedt erklæringen)

(certificate number / erklæringsnummer)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / sted, dato)

A. Speelman, CL Compliance Manager

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

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): SCF157

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

Philips

(brand name, nombre de la marca)

(Type version or model, Referencia o modelo)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(El organismo notificado)

(Name and number/ Nombre y número)

performed: Class I Rule 1

(realizador)

(description of intervention / descripción de la intervención)

and issued the certificate:

(Y expidió el certificado)

(certificate number / número de certificado)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / lugar, fecha)

A.Speelman, CL Compliance Manager

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

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): SCF157

(Ilmoitus seuraavista vastuullamme olevista sähkötuotteista:)

Philips

(brand name, Brändinimi)

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

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

(Viitaten seuraaviin yhdenmukaistettuihin standardeihin tai muihin teknisiin tietoihin:)

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Ilmoitettu laitos)

(Name and number/ Nimi ja numero)

performed: Class I Rule 1

(suoritetaan)

(description of intervention / toimenpiteen kuvaus)

and issued the certificate:

SRN: NL-MF-000001693

(Todistuksen antaja)

(certificate number / Sertifikaatin numero)

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / paikka, päiväys)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, márkanév)

(Type version or model, Típusváltozat vagy modell)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Bejelentett testület)

(Name and number/ Név és szám)

performed: Class I Rule 1

(teljesítve)

(description of intervention / intézkedés leírása)

and issued the certificate:

(és a kibocsátott tanúsítvány)

(certificate number / tanúsítvány száma)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / hely, dátum)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, marchio)

(Type version or model, modello o versione)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

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

performed: Class I Rule 1

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

and issued the certificate:

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

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / luogo e data)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, firmos ženklo pavadinimas)

(Type version or model, Tipas arba modelis)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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 nuolatinis dokumentus)

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

The Notified Body:

(Informuota įstaiga)

(Name and number/ Pavadinimas ir numeris)

performed: Class I Rule 1

(atlikta)

(description of intervention / intervencijos aprašymas)

and issued the certificate:

SRN: NL-MF-000001693

(Sertifikatas išleistas)

(certificate number / sertifikato numeris)

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:



Drachten, 19-Jun-25

(place, date / vieta, data)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(deklarēt zem vai atbildība ka, elektronisks produkts)

Philips

(brand name, fabrikas marka vārds)

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

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Reģistrēta galvenā daļa)

(Name and number/ vārds un numurs)

performed: Class I Rule 1

(paveikts)

(description of intervention / intervencijas apraksts)

and issued the certificate:

SRN: NL-MF-000001693

(Un izveido sertifikātu)

(certificate number / sertifikāta numurs)

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / vieta, datums)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, marka)

(Type version or model, Typ lub model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Jednostka certyfikująca)

(Name and number/ Nazwa i numer)

performed: Class I Rule 1

(wykonana)

(description of intervention / rodzaj badania)

and issued the certificate:

(i wydała certyfikat)

(certificate number / numer certyfikatu)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / miasto, data)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, nome da marca)

(Type version or model, Indicar versão ou modelo)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(O organismo notificado)

(Name and number/ Nome e número)

performed: Class I Rule 1

(realizada)

(description of intervention / descrição da intervenção)

and issued the certificate:

(E emitido o certificado)

(certificate number / certificado número)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / local, data)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, marca)

(Type version or model, Tip sau model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Organismul notificat)

(Name and number/ Nume și număr)

performed: Class I Rule 1

(a efectuat)

(description of intervention / descrierea intervenției)

and issued the certificate:

(Și a emis certificatul)

(certificate number / Numărul certificatului)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / locul, data)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(Декларируем под нашу ответственность, что электрическая продукция)

Philips

(brand name, торговая марка)

(Type version or model, тип, модель)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

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

performed: Class I Rule 1

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

and issued the certificate:

(и выпустил(а) сертификат)

(certificate number / номер сертификата)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / место, дата)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, názov značky)

(Type version or model, Typové označenie alebo model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Notifikovaný orgán)

(Name and number/ Názov a číslo)

performed: Class I Rule 1

(vykonan)

(description of intervention / opis zásahu)

and issued the certificate:

(A vydal osvedčenie)

(certificate number / číslo osvedčenia)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / miesto, dátum)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(S polno odgovornostjo izjavljamo)

Philips

(brand name, Ime znamke)

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

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Priglašeno organ)

(Name and number/ Ime in številka)

performed: Class I Rule 1

(Izvršeno)

(description of intervention / Opis ukrepa)

and issued the certificate:

(Izdaja certifikat)

(certificate number / Številka certifikata)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / Kraj, datum)

A. Speelman, CL Compliance Manager

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

3628

07/2011

(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 SCF157

(Bu uygunluk beyanı yalnızca imalatçının kendi sorumluluğu altında düzenlenir)

Philips

(Type version or model, Tip veya model)

(brand name, İsim)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Yetkili Kurul)

(Name and number/ İsim ve numara)

performed: Class I Rule 1

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

and issued the certificate:

(sertifikayı düzenlemiştir)

(certificate number / sertifika numarası)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / Yer ve tarih)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(Odgovorno izjavljujemo da je električni uređaj(i))

Philips

(brand name, Naziv robne marke)

(Type version or model, Tipska oznaka ili model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Nadležno tijelo)

(Name and number/ Ime i broj)

performed: Class I Rule 1

(Izveden)

(description of intervention / Opis intervencije)

and issued the certificate:

(Izdana je potvrda)

(certificate number / Broj potvrde)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / Mjesto, datum)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

(Δηλώνουμε υπεύθυνα ότι το ηλεκτρολογικό προϊόν/ προϊόντα)

Philips

(brand name, ονομασία μάρκας)

(Type version or model, Τύπος έκδοσης ή μοντέλο)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

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

performed: Class I Rule 1

(διεξήγαγε) (description of intervention / περιγραφή παρέμβασης)

and issued the certificate:

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

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / τόπος, ημερομηνία)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(Brand name, търговска марка)

(Type version or model, Серия или модел)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020

EN ISO 10993-5:2009

EN ISO 10993-10:2023

EN ISO 10993-18:2020 + A1:2023

EN ISO 10993-23:2021

EN ISO 14971:2019 + A1:2021

EN ISO 15223 – 1:2021

EN 20417:2021

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:

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

performed: Class I Rule 1

(извърши)

(description of intervention / описание на проверката)

and issued the certificate:

(И издаде сертификата)

(certificate number / номер на сертификата)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / място, дата)

A.Speelman, CL Compliance Manager

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

3628

07/2011

(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): SCF157

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

Philips

(brand name, naziv robne marke)

(Type version or model, Verzija tipa ili model)

Comfort Breast Shell

(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

Referring to the following harmonised standards or other technical specifications:

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

EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-18:2020 + A1:2023
EN ISO 10993-23:2021
EN ISO 14971:2019 + A1:2021
EN ISO 15223 – 1:2021
EN 20417:2021

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:

(Ovlašćeno telo)

(Name and number/ Naziv i broj)

performed: Class I Rule 1

(izvršeno)

(description of intervention / opis intervencije)

and issued the certificate:

(i izdat sertifikat)

(certificate number / broj sertifikata)

SRN: NL-MF-000001693

Risk Class: Class I

Basic UDI-DI: BUDI-DI: 8710103BM781JY

Remarks:

Drachten, 19-Jun-25

(place, date / potpis, ime i funkcija)

A.Speelman, CL Compliance Manager

(signature, name and function)