ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

(В съответствие с EN ISO/IEC 17050-1)

№ на декларацията:	**DOCIP 2051071**
Име и адрес на производителя / EU-AR:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

НАСТОЯЩАТА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ Е ИЗДАДЕНА НА ПЪЛНАТА ОТГОВОРНОСТ НА:

Име и адрес на производителя:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Идентификация на продукта:	**Smart Blood Pressure Monitor** **BTHBP10WT**

ПОСОЧЕНИТЕ В НАСТОЯЩАТА ДЕКЛАРАЦИЯ ПРОДУКТИ СА В СЪОТВЕТСТВИЕ СЪС:

законодателството на Общността:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Хармонизирани стандарти:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Други спецификации:	**Единен регистрационен номер (EPH): NL-IM-000028061** **Рисков клас: IIa** **Базов UDI-DI: 697204011AOJ30X17F**

Предназначение:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Нотифицирани органи:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Допълнителна информация:	**-**

ПОДПИСАНО ЗА И ОТ ИМЕТО НА:

Място и дата на издаване:	**'s Hertogenbosch, 11 юли 2023 г.**
Подпис:	
Име, длъжност:	**Gard Moors** **Мениджър по съответствието и качеството в Nedis**
Име на дружеството:	**NEDIS**

EU IZJAVA O SUKLADNOSTI

(U skladu s EN ISO/IEC 17050-1)

Broj izjave:	**DOCIP 2051071**
Ime i adresa proizvođača / EU-AR:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

OVA SE IZJAVA O SUGLASNOSTI IZDAJE POD ISKLJUČIVOM ODGOVORNOŠĆU:

Ime i adresa proizvođača:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identifikacija proizvoda:	**Smart Blood Pressure Monitor** **BTHBP10WT**

PROIZVOD SPOMENUT U OVOJ IZJAVI JE U SKLADU SA:

Zakonodavstvom Zajednice EU-a:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Usklađenim normama:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Ostale specifikacije:	**Jedinstveni registracijski broj („SRN”): NL-IM-000028061** **Klasa rizika: IIa** **Osnovni UDI-DI: 697204011AOJ30X17F**

Namjena:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Prijavljena tijela:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Dodatne informacije:	**-**

POTPISANO OD STRANE I U IME:

Mjesto i datum izdavanja:	**'s Hertogenbosch, 11. srpnja 2023.**
Potpis:	
Ime, funkcija:	**Gard Moors**
Ime društva:	**NEDIS**

EU PROHLÁŠENÍ O SHODĚ

(V souladu s normou EN ISO/IEC 17050-1)

Číslo prohlášení: **DOCIP 2051071**

Jméno a adresa výrobce / EU-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

TOTO PROHLÁŠENÍ O SHODĚ VYDAL NA VLASTNÍ ODPOVĚDNOST:

Jméno a adresa výrobce:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identifikace výrobku: **Smart Blood Pressure Monitor**
BTHBP10WT

VÝROBKY UVEDENÉ V TOMTO PROHLÁŠENÍ JSOU VE SHODĚ S:

Právními předpisy společenství EU:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmonizovanými normami:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Další specifikace:
Jediné registrační číslo: NL-IM-000028061
Riziková třída: IIa
Základní UDI-DI: 697204011AOJ30X17F

Určeným účelem:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Oznámené subjekty:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Doplňující informace:	**-**

PODEPSÁNO ZA A JMÉNEM:

Místo a datum vydání:	**'s Hertogenbosch, 11. července 2023**
Podpis:	
Jméno, funkce:	**Gard Moors** **Manažer shody a kvality Nedis**
Název společnosti:	**NEDIS**

EU-OVERENSSTEMMELSESERKLÆRING

(Ifølge normen EN ISO/IEC 17050-1)

Nr. af erklæring:	**DOCIP 2051071**
Navn og adresse på fabrikanten eller dennes bemyndigede repræsentant:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

DENNE OVERENSSTEMMELSESERKLÆRING UDSTEDES PÅ ANSVAR:

Navn og adresse på fabrikanten:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identifikation af produktet:	**Smart Blood Pressure Monitor** **BTHBP10WT**

GENSTANDEN FOR ERKLÆRINGEN, SOM BESKREVET OVENFOR, ER I OVERENSSTEMMELSE MED:

EF-harmoniseringslovgivning:

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmoniserede standarder:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Andre specifikationer:

Individuelt registreringsnummer (»SRN«): NL-IM-000028061
Risikoklasse: IIa
Grundlæggende UDI-DI: 697204011AOJ30X17F

Erklæret formål:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Bemyndigede organer:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Yderligere oplysninger:	**-**

UNDERSKREVET FOR OG PÅ VEGNE AF:

Sted og dato:	**'s Hertogenbosch, 11. juli 2023**
Underskrift:	
Navn, stilling:	**Gard Moors** **Compliance- og kvalitetschef Nedis**
Firmaets navn:	**NEDIS**

EU-CONFORMITEITSVERKLARING

(Volgens de norm EN ISO/IEC 17050-1)

No verklaring:	**DOCIP 2051071**
Naam en adres van de fabrikant of zijn gemachtigde:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

DEZE CONFORMITEITSVERKLARING WORDT VERSTREKT ONDER VOLLEDIGE VERANTWOORDELIJKHEID VAN:

Naam en adres van de fabrikant:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Productidentificatie:	**Smart Blood Pressure Monitor** **BTHBP10WT**

HET HIERBOVEN BESCHREVEN VOORWERP IS CONFORM:

EU-gemeenschapswetgeving:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Geharmoniseerde normen:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Overige specificaties:	**Uniek registratienummer („SRN”): NL-IM-000028061** **Risicoklasse: IIa** **Basic UDI-DI: 697204011AOJ30X17F**

Beoogd doeleind:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Aangemelde instanties:	**TÜV SÜD Product Service GmbH (0123)** **Certificaten: G10 103703 0006** **Modules: A**
Aanvullende informatie:	**-**

ONDERTEKEND VOOR EN NAMENS:

Plaats en datum van afgifte:	**'s Hertogenbosch, 11 juli 2023**
Handtekening:	
Naam, functie:	**Gard Moors** **Compliance & Quality manager Nedis**
Naam van het bedrijf:	**NEDIS**

EU DECLARATION OF CONFORMITY

(In accordance with EN ISO/IEC 17050-1)

Declaration number: **DOCIP 2051071**

Name and address of manufacturer / EU-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF:

Name and address of manufacturer:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Product identification: **Smart Blood Pressure Monitor**
BTHBP10WT

THE PRODUCTS MENTIONED IN THIS DECLARATION ARE IN CONFORMITY WITH:

EU Community Legislation:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmonised standards:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Other specifications:
Single registration number: NL-IM-000028061
Risk class: IIa
Basic UDI-DI: 697204011AOJ30X17F

Intended purpose:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Notified Body:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Additional information:	**-**

SIGNED FOR AND ON BEHALF OF:

Place and date of issue:	**'s Hertogenbosch, 11 July 2023**
Signature:	
Name, position:	**Gard Moors** **Compliance & Quality manager Nedis**
Company name:	**NEDIS**

ELI VASTAVUSDEKLARATSIOON

(Kooskõlas standardiga EN ISO/IEC 17050-1)

Dokumendi number: **DOCIP 2051071**

Tootja nimi ja aadress / EU-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

KÄESOLEV VASTAVUSDEKLARATSIOON ON VÄLJA ANTUD TOOTJA AINUVASTUTUSEL:

Tootja nimi ja aadress:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Toote identifitseerimisnumber:
Smart Blood Pressure Monitor
BTHBP10WT

KÄESOLEVAS VASTAVUSDEKLARATSIOONIS KIRJELDATUD TOOTED ON KOOSKÕLAS JÄRGMISTE ÕIGUSAKTIDEGA:

Euroopa Liidu õigusaktid:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmoneeritud standardite:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Muud tehnilised kirjeldused:
Unikaalse registreerimisnumbri : NL-IM-000028061
Riskiklass: IIa
Põhi-UDI-DI: 697204011AOJ30X17F

Sihtotstarve:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Teavitatud asutused:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Täiendav teave:	**-**

ALLA KIRJUTANUD (KELLE POOLT/NIMEL):

Väljaandmise aeg ja koht:	**'s Hertogenbosch, 11. juuli 2023**
Allkiri:	
Nimi, ametinimetus:	**Gard Moors** **Nõuetele vastavuse ja kvaliteedi juht Nedis**
Ettevõtte nimi:	**NEDIS**

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

(Normin mukaan EN ISO/IEC 17050-1)

Nro vakuutuksen:	**DOCIP 2051071**
Valmistajan ja hänen valtuutetun edustajansa nimi ja osoite:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

TÄMÄ VAATIMUSTENMUKAISUUSVAKUUTUS ON ANNETTU YKSINOMAISELLA VASTUULLA:

Valmistajan nimi ja osoite:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Tuotteen tunnistetiedot:	**Smart Blood Pressure Monitor** **BTHBP10WT**

EDELLÄ KUVATTU VAKUUTUS ON YHDENMUKAINEN:

EY yhteisön lainsäädännön vaatimusten mukainen:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Yhdenmukaistettuihin standardeihin:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Muut tiedot:	**Rekisterinumero: NL-IM-000028061** **Riskiluokka: IIa** **Yksilöllisen UDI-DI: 697204011AOJ30X17F**

Käyttötarkoituksella:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Ilmoitetut laitokset:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Lisätietoja:	**-**

ALLEKIRJOITTU SINUSTA JA PUOLESTA:

Antamispaikka ja –päivämäärä:	**'s Hertogenbosch, 11. heinäkuuta 2023**
Allekirjoitus:	
Nimi, tehtävä:	**Gard Moors** **Vaatimusten noudattamisesta ja laadusta vastaava johtaja Nedis**
Yrityksen nimi:	**NEDIS**

DÉCLARATION UE DE CONFORMITÉ

(Selon la norme EN ISO/IEC 17050-1)

No DÉCLARATION : **DOCIP 2051071**

Nom et adresse du fabricant ou de son mandataire:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

LA PRÉSENTE DÉCLARATION DE CONFORMITÉ EST ÉTABLIE SOUS LA SEULE RESPONSABILITÉ DU:

Nom et adresse du fabricant:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identification du produit: **Smart Blood Pressure Monitor**
BTHBP10WT

L'OBJET DE LA DÉCLARATION DÉCRIT CI-DESSUS EST CONFORME À:

UE Législation communautaire:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Normes harmonisées:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Autres spécifications:
Numéro d'enregistrement unique: NL-IM-000028061
Classe de risque: IIa
IUD-ID de base: 697204011AOJ30X17F

Destination:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Organismes notifiés:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Informations supplémentaires:	**-**

SIGNÉ PAR ET AU NOM DE:

Date et lieu d'établissement:	**'s Hertogenbosch, 11 juillet 2023**
Signature:	
Nom, fonction:	**Gard Moors** **Responsable de la conformité et de la qualité Nedis**
Nom du fabricant:	**NEDIS**

EU-KONFORMITÄTSERKLÄRUNG

(Gemäß der Norm EN ISO/IEC 17050-1)

No Erklärung: **DOCIP 2051071**

Name und Anschrift des Herstellers oder seines Bevollmächtigten:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

DIE ALLEINIGE VERANTWORTUNG FÜR DIE AUSSTELLUNG DIESER KONFORMITÄTSERKLÄRUNG TRÄGT:

Name und Anschrift des Herstellers:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Produktidentifikation: **Smart Blood Pressure Monitor**
BTHBP10WT

DER OBEN BESCHRIEBENE GEGENSTAND DER ERKLÄRUNG ERFÜLLT:

EU-Gemeinschaftsrecht:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmonisierte Normen:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Andere Spezifikationen:
Einmalige Registrierungsnummer („SRN“): NL-IM-000028061
Risikoklasse: IIa
Basis-UDI-DI: 697204011AOJ30X17F

Zweckbestimmung:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Benannte Stellen:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Zusätzliche Informationen:	**-**

UNTERZEICHNET FÜR UND IM NAMEN VON:

Ort und Datum der Ausstellung:	**'s Hertogenbosch, 11. Juli 2023**
Unterschrift:	
Name, Funktion:	**Gard Moors** **Manager für Einhaltung und Qualität Nedis**
Name des Unternehmens:	**NEDIS**

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

(Σύμφωνα με το πρότυπο EN ISO/IEC 17050-1)

Αριθμός δήλωσης:	**DOCIP 2051071**
Επωνυμία και διεύθυνση του κατασκευαστή / EU-AR:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

Η ΠΑΡΟΥΣΑ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΚΔΙΔΕΤΑΙ ΥΠΟ ΤΗΝ ΑΠΟΚΛΕΙΣΤΙΚΗ ΕΥΘΥΝΗ:

Επωνυμία και διεύθυνση του κατασκευαστή:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Αριθμός ταυτοποίησης προϊόντος:	**Smart Blood Pressure Monitor** **BTHBP10WT**

ΤΑ ΠΡΟΪΟΝΤΑ ΠΟΥ ΑΝΑΦΕΡΟΝΤΑΙ ΣΤΗΝ ΠΑΡΟΥΣΑ ΔΗΛΩΣΗ ΕΙΝΑΙ ΣΥΜΜΟΡΦΑ ΜΕ:

Κοινοτική νομοθεσία της ΕΕ:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Εναρμονισμένα πρότυπα:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Λοιπές προδιαγραφές:	**Ενιαίο αριθμό καταχώρισης («SRN»): NL-IM-000028061** **Κατηγορία κινδύνου: IIa** **Βασική UDI-DI: 697204011AOJ30X17F**

Προβλεπόμενη χρήση:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Κοινοποιημένοι οργανισμοί:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Συμπληρωματικές πληροφορίες:	**-**

ΥΠΟΓΡΑΦΗ ΓΙΑ ΛΟΓΑΡΙΑΣΜΟ ΚΑΙ ΕΞ ΟΝΟΜΑΤΟΣ:

Τόπος και ημερομηνία έκδοσης:	**'s Hertogenbosch, 11 Ιουλίου 2023**
Υπογραφή:	
Όνομα, θέση:	**Gard Moors** **Διευθυντής συμμόρφωσης και ποιότητας Nedis**
Επωνυμία εταιρείας:	**NEDIS**

EU-MEGFELELŐSÉGI NYILATKOZAT

(Az EN ISO/IEC 17050-1 szabvány alapján)

A nyilatkozat száma:	**DOCIP 2051071**
A gyártó vagy meghatalmazott képviselőjének neve és címe:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

EZT A MEGFELELŐSÉGI NYILATKOZATOT A GYÁRTÓ KIZÁRÓLAGOS FELELŐSSÉGE MELLETT ADJÁK KI:

A gyártó neve és címe:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
A termék azonosítása:	**Smart Blood Pressure Monitor** **BTHBP10WT**

A FENT ISMERTETETT NYILATKOZAT TÁRGYA MEGFELEL AZ ALÁBBI KÖZÖSSÉGI HARMONIZÁCIÓS JOGSZABÁLYNAK:

Közösségi harmonizációs jogszabály:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Harmonizált szabványoknak:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Egyéb előírások:	**Egyedi regisztrációs szám: NL-IM-000028061** **Kockázati osztálya: IIa** **Basic UDI-DI: 697204011AOJ30X17F**

Rendeltetés:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Bejelentett szervek:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Kiegészítő információk:	**-**

A NYILATKOZATOT A KÖVETKEZŐ SZEMÉLY NEVÉBEN ÉS RÉSZÉRŐL ÍRTÁK ALÁ:

A kiállítás helye és dátuma:	**'s Hertogenbosch, 2023. július 11.**
Aláírás:	
Név, beosztás:	**Gard Moors** **Megfelelési és minőségügyi vezető Nedis**
A társaság neve:	**NEDIS**

DICHIARAZIONE DI CONFORMITÀ UE

(Secondo la norma EN ISO/IEC 17050-1)

N. di dichiarazione: **DOCIP 2051071**

Nome ed indirizzo del fabbricante o del suo rappresentante autorizzato:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

LA PRESENTE DICHIARAZIONE DI CONFORMITÀ È RILASCIATA SOTTO LA RESPONSABILITÀ ESCLUSIVA DE:

Nome e indirizzo del produttore:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identificazione di prodotto:
Smart Blood Pressure Monitor
BTHBP10WT

L'OGGETTO DELLA DICHIARAZIONE DI CUI SOPRA È CONFORME A:

Legislazione comunitaria di armonizzazione:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Norme armonizzate:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Altre specifiche:
Numero di registrazione unico: NL-IM-000028061
Classe di rischio: IIa
UDI-DI di base: 697204011AOJ30X17F

Destinazione d'uso:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Organismi notificati:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Informazioni supplementari:	**-**

FIRMATO IN VECE E PER CONTO DI:

Luogo e data del rilascio:	**'s Hertogenbosch, 11 luglio 2023**
Firma:	
Nome e cognome, funzione:	**Gard Moors** **Responsabile conformità e qualità Nedis**
Nome dell'azienda:	**NEDIS**

ES ATBILSTĪBAS DEKLARĀCIJA

(pēc EN ISO/IEC 17050-1)

Nr. deklarācija:	**DOCIP 2051071**
Ražotāja vai viņa pilnvarotā pārstāvja vārds/nosaukums un adrese:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

ŠĪ ATBILSTĪBAS DEKLARĀCIJA IR IZDOTA VIENĪGI UZ:

Ražotāja vārds/nosaukums un adrese:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Produkta identifikācija:	**Smart Blood Pressure Monitor** **BTHBP10WT**

IEPRIEKŠ APRAKSTĪTA PRIEKŠMETS ATBILST:

Deklarācijas attiecīgajam Kopienas saskaņotajam tiesību aktam:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Piemērojamajiem standartiem:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Citas specifikācijas:	**Vienotu reģistrācijas numuru (VRN): NL-IM-000028061** **Riska klase: IIa** **Pamata UDI-DI: 697204011AOJ30X17F**

Paredzētais nolūks:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Paziņotās struktūras:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Papildu informācija:	**-**

PARAKSTĪTS TĀ UN VĀRDĀ:

Izdošanas vieta un datums:	**'s Hertogenbosch, 2023. gada 11. jūlijs**
Paraksts:	
Vārds, uzvārds, amats:	**Gard Moors** **Atbilstības un kvalitātes vadītājs Nedis**
Kompānijas nosaukums:	**NEDIS**

ES ATITIKTIES DEKLARACIJA

(įforminta pagal EN ISO/IEC 17050-1)

Nr. Deklaracijos:	**DOCIP 2051071**
Gamintojo arba jo įgaliotojo atstovo pavadinimas ir adresas:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

ŠI ATITIKTIES DEKLARACIJA IŠDUODAMA IŠIMTINĖS ATSAKOMYBĖS:

Gamintojo pavadinimas ir adresas:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Gaminio identifikavimo:	**Smart Blood Pressure Monitor** **BTHBP10WT**

PIRMIAU APRAŠYTAS OBJEKTAS ATITINKA:

EB Bendrijos derinimo teisės aktai:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Darniųjų standartų:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Kitos specifikacijos:	**Unikalųjį registracijos numerį: NL-IM-000028061** **Rizikos klasė: IIa** **Bazinis UDI-DI: 697204011AOJ30X17F**

Numatyta paskirtis:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Notifikuotosios įstaigos:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Papildoma informacija:	**-**

UŽ KĄ IR KIENO VARDU PASIRAŠYTA:

Išdavimo vieta ir data: **'s Hertogenbosch, 2023 m. liepos 11 d.**

Parašas:

Pavardė, pareigos: **Gard Moors**
Atitikties ir kokybės vadovas Nedis

Įmonės pavadinimas: **NEDIS**

DIKJARAZZJONI TAL-KONFORMITÀ TAL-UE

(Skont EN ISO/IEC 17050-1)

Numru tad-dikjarazzjoni: **DOCIP 2051071**

L-isem u l-indirizz tal-manifattur / EU-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

DIN ID-DIKJARAZZJONI TAL-KONFORMITÀ QED TINĦAREĠ TAĦT IR-RESPONSABBILTÀ UNIKA TA':

L-isem u l-indirizz tal-manifattur:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identifikazzjoni tal-prodott:
Smart Blood Pressure Monitor
BTHBP10WT

IL-PRODOTTI MSEMMIJA F'DIN ID-DIKJARAZZJONI HUMA F'KONFORMITÀ MA':

Leġiżlazzjoni Komunitarja tal-UE:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Standards armonizzati:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Speċifikazzjonijiet oħra:
Numru ta' reġistrazzjoni uniku ("SRN"): NL-IM-000028061
Klassi tar-riskju: IIa
UDI-DI Bażiku: 697204011AOJ30X17F

Għan maħsub:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Korpi notifikati:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Informazzjoni addizzjonali:	**-**

IFFIRMATA GĦAL U F'ISEM:

Post u data tal-ħruġ:	**'s Hertogenbosch, 11 ta' Lulju 2023**
Firma:	
Isem, kariga:	**Gard Moors**
Isem tal-kumpanija:	**NEDIS**

DEKLARACJA ZGODNOŚCI UE

(Zgodnie z normą EN ISO/IEC 17050-1)

Nr deklaracja:	**DOCIP 2051071**
Nazwa i adres producenta lub jego upoważnionego przedstawiciela:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

NINIEJSZA DEKLARACJA ZGODNOŚCI WYDANA ZOSTAJE NA WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ:

Nazwa i adres producenta:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identyfikator produktu:	**Smart Blood Pressure Monitor** **BTHBP10WT**

WYMIENIONY POWYŻEJ PRZEDMIOT NINIEJSZEJ DEKLARACJI JEST ZGODNY Z:

Wspólnotowych przepisów harmonizacyjnych WE:

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Norm zharmonizowanych:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Inne specyfikacje:

Niepowtarzalny numer rejestracyjny: NL-IM-000028061
Klasa ryzyka: IIa
Basic UDI–DI: 697204011AOJ30X17F

Przewidziane zastosowanie:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Jednostki notyfikowane:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Dodatkowe informacje:	**-**

PODPISANO W IMIENIU:

Miejsce i data wydania:	**'s Hertogenbosch, 11 lipca 2023**
Podpis:	
Nazwisko, stanowisko:	**Gard Moors** **Kierownik ds. zgodności i jakości Nedis**
Nazwa firmy:	**NEDIS**

DECLARAÇÃO UE DE CONFORMIDADE

(De acordo com a norma EN ISO/IEC 17050-1)

No declaração:	**DOCIP 2051071**
Nome e endereço do fabricante ou do respectivo mandatário:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

A PRESENTE DECLARACÃO DE CONFORMIDADE É EMITIDA SOB A EXCLUSIVA RESPONSABILIDADE DO:

Nome e endereço do fabricante:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identificação do produto:	**Smart Blood Pressure Monitor** **BTHBP10WT**

O OBJECTO DA DECLARACÃO ACIMA MENCIONADA ESTÁ EM CONFORMIDADE COM:

Legislação comunitária da UE:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Padrões harmonizados:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Outras especificações:	**Número único de registo: NL-IM-000028061** **Classe de risco: IIa** **UDI-DI básico: 697204011AOJ30X17F**

Finalidade prevista:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Organismos notificados:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Informações suplementares:	**-**

ASSINADO POR E EM NOME DE:

Local e data da emissão:	**'s Hertogenbosch, 11 de julho de 2023**
Assinatura:	
nome, cargo:	**Gard Moors** **Diretor de conformidade e qualidade Nedis**
Nome da empresa:	**NEDIS**

DECLARAȚIA UE DE CONFORMITATE

(În conformitate cu EN ISO/IEC 17050-1)

Declarația numărul: **DOCIP 2051071**

Denumirea și adresa producătorului / UE-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

ACEASTĂ DECLARAȚIE DE CONFORMITATE ESTE EMISĂ PE RĂSPUNDEREA EXCLUSIVĂ A:

Denumirea și adresa producătorului:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identificarea produsului: **Smart Blood Pressure Monitor BTHBP10WT**

PRODUSELE MENȚIONATE ÎN ACEASTĂ DECLARAȚIE SUNT ÎN CONFORMITATE CU:

Legislația comunitară a UE:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Standardelor armonizate:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Alte specificații:
Număr unic de înregistrare (SRN): NL-IM-000028061
Clasa de risc: IIa
UDI-DI de bază: 697204011AOJ30X17F

Scop propus:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Organisme notificate:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Informații suplimentare:	**-**

SEMNAT PENTRU ȘI ÎN NUMELE:

Locul și data emiterii:	**'s Hertogenbosch, 11 iulie 2023**
Semnătura:	
Numele, funcția:	**Gard Moors** **Manager de conformitate și calitate Nedis**
Denumirea societății:	**NEDIS**

EÚ VYHLÁSENIE O ZHODE

(V súlade s normou EN ISO/IEC 17050-1)

Číslo vyhlásenia: **DOCIP 2051071**

Meno a adresa výrobcu/EU-AR:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

TOTO VYHLÁSENIE O ZHODE SA VYDÁVA NA VÝHRADNÚ ZODPOVEDNOSŤ:

Meno a adresa výrobcu:
NEDIS
De Tweeling 28
5215 MC 's Hertogenbosch
Netherlands

Identifikácia výrobku: **Smart Blood Pressure Monitor**
BTHBP10WT

VÝROBKY UVEDENÉ V TOMTO VYHLÁSENÍ SÚ V ZHODE S:

Právne predpisy Spoločenstva:
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Harmonizovanými normami:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Ďalšie špecifikácie:
Jediné registračné číslo („SRN“): NL-IM-000028061
Riziková trieda: IIa
Základný UDI-DI: 697204011AOJ30X17F

Účel určenia:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Notifikované osoby:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Doplňujúce informácie:	**-**

PODPÍSANÉ ZA A V MENE:

Dátum a miesto vydania:	**'s Hertogenbosch, 11. júla 2023**
Podpis:	
Meno, funkcia:	**Gard Moors** **Manažér pre súlad a kvalitu Nedis**
Názov spoločnosti:	**NEDIS**

IZJAVA EU O SKLADNOSTI

(v skladu s standardom EN ISO/IEC 17050-1)

Številka izjave:	**DOCIP 2051071**
Ime in naslov proizvajalca/EU-AR:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

ZA IZDAJO TE IZJAVE O SKLADNOSTI JE ODGOVOREN IZKLJUČNO:

Ime in naslov proizvajalca:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identifikacija proizvoda:	**Smart Blood Pressure Monitor** **BTHBP10WT**

IZDELKI, OMENJENI V TEJ IZJAVI, SO V SKLADU Z:

Zakonodaja Skupnosti EU:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Harmoniziranimi standardi:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Druge specifikacije:	**Enotna registrska številka: NL-IM-000028061** **Razred tveganja: IIa** **Osnovni UDI-DI: 697204011AOJ30X17F**

Predvideni namen:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Priglašeni organi:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Dodatne informacije:	**-**

PODPISANO ZA IN V IMENU:

Kraj in datum izdaje:	**'s Hertogenbosch, 11. julij 2023**
Podpis:	
Ime, funkcija:	**Gard Moors** **Vodja za skladnost in kakovost Nedis**
Ime podjetja:	**NEDIS**

DECLARACIÓN UE DE CONFORMIDAD

(De acuerdo con la norma EN ISO/IEC 17050-1)

No Declaración:	**DOCIP 2051071**
Nombre y dirección del fabricante / UE representante autorizado:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

LA PRESENTE DECLARACIÓN DE CONFORMIDAD SE EXPIDE BAJO LA EXCLUSIVA RESPONSABILIDAD DE:

Nombre y dirección del fabricante:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identificación del producto:	**Smart Blood Pressure Monitor** **BTHBP10WT**

EL PRODUCTO DE LA DECLARACIÓN DESCRITA ANTERIORMENTE ES CONFORME CON:

UE legislación comunitaria:

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]
Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]
Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]

Normas armonizadas:

Medical devices
EN 60601-1-11:2015
EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12
EN 62304:2006 + AC:2008 + A1:2015
EN ISO 13485:2016 + AC:2018 + A11:2021
EN ISO 14155:2020
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021
EN ISO 81060-1:2012
EN ISO 81060-2:2019

Safety of electrical equipment
EN 62368-1:2014 + A11:2017

Radio equipment
EN 300 328 V2.2.2

Exposure of humans to electromagnetic fields (EMF)
EN IEC 62311:2020 + EN 62311:2008
EN 62479:2010

Electromagnetic Compatibility (EMC)
EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2
EN 301 489-17 V3.2.4
EN 60601-1-2:2015 + A1:2021

Restricted substances in electrical products
EN IEC 63000:2018

Otras especificaciones:

Número de registro único («SRN»): NL-IM-000028061
Clase de riesgo: IIa
UDI-DI básico: 697204011AOJ30X17F

Finalidad prevista:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Organismos notificados:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Información complementaria:	**-**

FIRMADO POR Y EN NOMBRE DE:

Lugar y fecha de expedición:	**'s Hertogenbosch, 11 de julio de 2023**
Firma:	
Nombre, cargo:	**Gard Moors** **Responsable de conformidad y calidad Nedis**
Nombre de la empresa:	**NEDIS**

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

(Enligt normen EN ISO/IEC 17050-1)

Nr deklaration:	**DOCIP 2051071**
Namn på och adress till tillverkaren eller dennes representant:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**

DENNA FÖRSÄKRAN OM ÖVERENSSTÄMMELSE UTFÄRDAS EGET ANSVAR:

Namn på och adress till tillverkaren:	**NEDIS** **De Tweeling 28** **5215 MC 's Hertogenbosch** **Netherlands**
Identifiera produkten:	**Smart Blood Pressure Monitor** **BTHBP10WT**

FÖREMÅLET FÖR FÖRSÄKRAN OVAN ÖVERENSSTÄMMER MED:

EG relevanta harmoniserade gemenskapslagstiftningen:	**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU [OJEU L174/88-110, 01.07.2011]** **Medical Devices Regulation (EU) 2017/745 [OJEU L117/1-175, 05.05.2017]** **Radio Equipment Directive (RED) 2014/53/EU [OJEU L153/62-106, 22.05.2014]**
Harmoniserade standarder:	**Medical devices** EN 60601-1-11:2015 EN 60601-1:2006 + AC:2010 + A1:2013 + AC:2014 + A12:2014 + A2:2021 + AC:2022-12 EN 62304:2006 + AC:2008 + A1:2015 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14155:2020 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN ISO 81060-1:2012 EN ISO 81060-2:2019 **Safety of electrical equipment** EN 62368-1:2014 + A11:2017 **Radio equipment** EN 300 328 V2.2.2 **Exposure of humans to electromagnetic fields (EMF)** EN IEC 62311:2020 + EN 62311:2008 EN 62479:2010 **Electromagnetic Compatibility (EMC)** EN 301 489-1 V2.1.1 + EN 301 489-1 V2.2.3 + EN 301 489-1 V1.9.2 EN 301 489-17 V3.2.4 EN 60601-1-2:2015 + A1:2021 **Restricted substances in electrical products** EN IEC 63000:2018
Övriga specifikationer:	**Eudamed-registreringsnummer (SRN) : NL-IM-000028061** **Riskklass: IIa** **Grundläggande UDI-DI: 697204011AOJ30X17F**

Avsett ändamål:	**The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home**
Anmälda organ:	**TÜV SÜD Product Service GmbH (0123)** **Certificates: G10 103703 0006** **Modules: A**
Ytterligare information:	**-**

UNDERTECKNAT FÖR:

Ort och datum:	**'s Hertogenbosch, 11 juli 2023**
Namnteckning:	
Namn, befattning:	**Gard Moors** **Chef för efterlevnad och kvalitet Nedis**
Namnet på företaget:	**NEDIS**