

# ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

(В съответствие с EN ISO/IEC 17050-1)

№ на декларацията: **DOCIP 2051083**  
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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
EN 60601-1-2:2015 + A1:2021

**Restricted substances in electrical products**  
EN IEC 63000:2018

Други спецификации: **Единен регистрационен номер (EPN): NL-IM-000028061  
Рисков клас: IIa  
Базов UDI-DI: 697204011A0J20X178**

Предназначение: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Нотифицирани органи: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**ПОДПИСАНО ЗА И ОТ ИМЕТО НА:**

Място и дата на издаване: **'s Hertogenbosch, 19 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Namjena: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Prijavljena tijela: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**POTPISANO OD STRANE I U IME:**

Mjesto i datum  
izdavanja: **'s Hertogenbosch, 19. srpnja 2023.**

Potpis:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

Ime, funkcija: **Gard Moors**

Ime društva: **NEDIS**

# EU PROHLÁŠENÍ O SHODĚ

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

Číslo prohlášení: **DOCIP 2051083**  
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 Infrared Thermometer**  
**BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Určeným účelem: **The product is intended to measure human body temperature via the**  
**eardrum for people over 3 months or via the forehead for people of**  
**asll ages for professional use or home use**

Oznámené subjekty: **TÜV SÜD Product Service GmbH (0123)**  
**Certificates: G2 1037030001**  
**Modules: A**

**PODEPSÁNO ZA A JMÉNEM:**

Místo a datum vydání: **'s Hertogenbosch, 19. července 2023**

Podpis:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011A0J20X178**

Erklæret formål: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Bemyndigede organer: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**UNDERSKREVET FOR OG PÅ VEGNE AF:**

Sted og dato: **'s Hertogenbosch, 19. juli 2023**

Underskrift:

A handwritten signature in black ink, appearing to be 'G.M.', with a horizontal line extending to the right.

Navn, stilling: **Gard Moors  
Compliance- og kvalitetschef Nedis**

Firmaets navn: **NEDIS**



# EU-CONFORMITEITSVERKLARING

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

No verklaring: **DOCIP 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Beoogd doeleind: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Aangemelde instanties: **TÜV SÜD Product Service GmbH (0123)  
Certificaten: G2 1037030001  
Modules: A**

**ONDERTEKEND VOOR EN NAMENS:**

Plaats en datum van afgifte: **'s Hertogenbosch, 19 juli 2023**

Handtekening:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Intended purpose: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Notified Body: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**SIGNED FOR AND ON BEHALF OF:**

Place and date of issue: **'s Hertogenbosch, 19 July 2023**

Signature:

A handwritten signature in black ink, appearing to be 'G.M.', written over a horizontal line.

Name, position: **Gard Moors  
Compliance & Quality manager Nedis**

Company name: **NEDIS**

# ELI VASTAVUSDEKLARATSIOON

(Kooskõlas standardiga EN ISO/IEC 17050-1)

Dokumendi number: **DOCIP 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: Ila  
Põhi-UDI-DI: 697204011AOJ20X178**

Sihtotstarve: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
asll ages for professional use or home use**

Teavitatud asutused: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**ALLA KIRJUTANUD (KELLE POOLT/NIMEL):**

Väljaandmise aeg ja koht: **'s Hertogenbosch, 19. 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Käyttötarkoituksella: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Ilmoitetut laitokset: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**ALLEKIRJOITTU SINUSTA JA PUOLESTA:**

Antamispaikka ja -  
päivämäärä:

**'s Hertogenbosch, 19. 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Destination: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Organismes notifiés: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**SIGNÉ PAR ET AU NOM DE:**

Date et lieu  
d'établissement:

**'s Hertogenbosch, 19 juillet 2023**

Signature:

A handwritten signature in black ink, appearing to be 'Gard Moors', written over a horizontal line.

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Zweckbestimmung: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Benannte Stellen: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**UNTERZEICHNET FÜR UND IM NAMEN VON:**

Ort und Datum der Ausstellung: **'s Hertogenbosch, 19. Juli 2023**

Unterschrift:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

Name, Funktion: **Gard Moors  
Manager für Einhaltung und Qualität Nedis**

Name des Unternehmens: **NEDIS**

# ▲Η▲ΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

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

Αριθμός δήλωσης: **DOCIP 2051083**  
Επωνυμία και διεύθυνση του κατασκευαστή / EU-AR: **NEDIS  
De Tweeling 28  
5215 MC 's Hertogenbosch  
Netherlands**



## Η ΠΑΡΟΥΣΑ ▲Η▲ΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΚΔΙΔΕΤΑΙ ΥΠΟ ΤΗΝ ΑΠΟΚΛΕΙΣΤΙΚΗ ΕΥΘΥΝΗ:

Επωνυμία και διεύθυνση του κατασκευαστή: **NEDIS  
De Tweeling 28  
5215 MC 's Hertogenbosch  
Netherlands**  
Αριθμός ταυτοποίησης προϊόντος: **Smart Infrared Thermometer  
BTHTIR10WT**



## ΤΑ ΠΡΟΪΟΝΤΑ ΠΟΥ ΑΝΑΦΕΡΟΝΤΑΙ ΣΤΗΝ ΠΑΡΟΥΣΑ ▲Η▲ΩΣΗ 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011A0J20X178**

Προβλεπόμενη χρήση: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Κοινοποιημένοι οργανισμοί: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**ΥΠΟΓΡΑΦΗ ΓΙΑ ▲ΟΓΑΡΙΑΣΜΟ ΚΑΙ ΕΞ ΟΝΟΜΑΤΟΣ:**

Τόπος και ημερομηνία έκδοσης: **'s Hertogenbosch, 19 Ιουλίου 2023**

Υπογραφή:



Όνομα, θέση: **Gard Moors**  
**▲ιευθυντής συμμόρφωσης και ποιότητας Nedis**

Επωνυμία εταιρείας: **NEDIS**

# EU-MEGFELELŐSÉGI NYILATKOZAT

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

A nyilatkozat száma: **DOCIP 2051083**

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 Infrared Thermometer  
BTHIR10WT**



**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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Rendeltetés: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Bejelentett szervek: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**A NYILATKOZATOT A KÖVETKEZŐ SZEMÉLY NEVÉBEN ÉS RÉSZÉRŐL ÍRTÁK ALÁ:**

A kiállítás helye és  
dátuma:

**'s Hertogenbosch, 2023. július 19.**

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011A0J20X178**

Destinazione d'uso: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Organismi notificati: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**FIRMATO IN VECE E PER CONTO DI:**

Luogo e data del rilascio: **'s Hertogenbosch, 19 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Paredzētais nolūks: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Paziņotās struktūras: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**PARAKSTĪTS TĀ UN VĀRDĀ:**

Izdošanas vieta un  
datums:

**'s Hertogenbosch, 2023. gada 19. 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011A0J20X178**

Numatyta paskirtis: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Notifikuotosios įstaigos: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**UŽ KĄ IR KIENO VARDU PASIRAŠYTA:**

Išdavimo vieta ir data: **'s Hertogenbosch, 2023 m. liepos 19 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 2051083**

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



## DIN ID-DIKJARAZZJONI TAL-KONFORMITÀ QED TINHAREĠ TAHT IR-RESPONSABBILTÀ UNIKA TA':

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

Identifikazzjoni tal-prodott: **Smart Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Għan maħsub: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Korpi notifikati: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

## IFFIRMATA GĦAL U F'ISEM:

Post u data tal-ħruġ: **'s Hertogenbosch, 19 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Przewidziane  
zastosowanie: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
asll ages for professional use or home use**

Jednostki notyfikowane: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**



**PODPISANO W IMIENIU:**

Miejsce i data wydania: **'s Hertogenbosch, 19 lipca 2023**

Podpis:

A handwritten signature in black ink, appearing to be 'Gard Moors', written over a horizontal line.

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 2051083**

Nome e endereço do fabricante ou do respectivo mandatário: **NEDIS  
De Tweeling 28  
5215 MC 's Hertogenbosch  
Netherlands**



## A PRESENTE DECLARAÇÃO 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 Infrared Thermometer  
BTHTIR10WT**



## O OBJECTO DA DECLARAÇÃO 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Finalidade prevista: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Organismos notificados: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**ASSINADO POR E EM NOME DE:**

Local e data da emissão: **'s Hertogenbosch, 19 de julho de 2023**

Assinatura:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Scop propus: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Organisme notificate: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**SEM NAT PENTRU ȘI ÎN NUMELE:**

Locul și data emiterii: **'s Hertogenbosch, 19 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Účel určenia: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Notifikované osoby: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**PODPÍSANÉ ZA A V MENE:**

Dátum a miesto vydania: **'s Hertogenbosch, 19. 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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Predvideni namen: **The product is intended to measure human body temperature via the  
eardrum for people over 3 months or via the forehead for people of  
all ages for professional use or home use**

Priglašeni organi: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**



**PODPISANO ZA IN V IMENU:**

Kraj in datum izdaje: **'s Hertogenbosch, 19. julij 2023**

Podpis:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a long horizontal stroke extending to the right.

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 2051083**

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 Infrared Thermometer  
BTHTIR10WT**



## 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011A0J20X178**

Finalidad prevista: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Organismos notificados: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**FIRMADO POR Y EN NOMBRE DE:**

Lugar y fecha de expedición:

**'s Hertogenbosch, 19 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 2051083**

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



## DENNA FÖRSÄKAN OM ÖVERENSSTÄMMELSE UTFÄRDAS EGET ANSVAR:

Namn på och adress till tillverkaren: **NEDIS  
De Tweeling 28  
5215 MC 's Hertogenbosch  
Netherlands**

Identifiera produkten: **Smart Infrared Thermometer  
BTHTIR10WT**



## FÖREMÅLET FÖR FÖRSÄKAN 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]**

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 14971:2019 + A11:2021  
EN ISO 15223-1:2021

**Electromagnetic Compatibility (EMC)**  
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: 697204011AOJ20X178**

Avsett ändamål: **The product is intended to measure human body temperature via the eardrum for people over 3 months or via the forehead for people of all ages for professional use or home use**

Anmälda organ: **TÜV SÜD Product Service GmbH (0123)  
Certificates: G2 1037030001  
Modules: A**

**UNDERTECKNAT FÖR:**

Ort och datum: **'s Hertogenbosch, 19 juli 2023**

Namnsteckning:

A handwritten signature in black ink, appearing to read 'Gard Moors', with a horizontal line extending to the right.

Namn, befattning: **Gard Moors  
Chef för efterlevnad och kvalitet Nedis**

Namnet på företaget: **NEDIS**