

DECLARATION OF CONFORMITY

KONFORMITÄTSEKTLÄRUNG
DÉCLARATION DE CONFORMITÉ
DICHIARAZIONE DI CONFORMITÀ
VERKLARING VAN OVEREENSTEMMING
DECLARACIÓN DE CONFORMIDAD
DECLARAÇÃO DE CONFORMIDADE
FÖRSÄKRAN OM ÖVERENSSTÄMMELSE
OVERENSSTEMMELSESERKLÆRING
SAMSVARERKLÆRING
VAATIMUSTENMUKAISUUSVAKUUTUS
DEKLARACJA ZGODNOŚCI
PROHLÁŠENÍ O SHODĚ

Manufacturer's Name: Medela AG

(Name des Herstellers / Nom du fabricant / Nome del produttore / Naam fabrikant / Nombre del fabricante / Nome do fabricante / Tillverkarens namn / Producentens navn / Produsentens navn / Valmistajan nimi / Nazwa producenta / Jméno výrobce)

Business Address: Lättichstrasse 4b, 6340 Baar, Switzerland

(Geschäftsadresse / Adresse commerciale / Indirizzo aziendale / Vestigingsadres / Dirección de la empresa / Endereço comercial / Företagsadress / Virksomhedsadresse / Selskapets adresse / Yrityksen osoite / Adres firmy / Sídlo)

We declare under our sole responsibility, that the following product(s) is (are) in conformity with the requirements of the below mentioned directives/regulations and standards.

Wir erklären in eigener Verantwortung, dass die folgenden Produkte den nachstehenden Richtlinien und Normen entsprechen.

Nous déclarons, sous notre unique responsabilité, que les produits suivants sont conformes aux directives et normes mentionnées ci-dessous.

Dichiariamo sotto la nostra esclusiva responsabilità che i seguenti prodotti sono conformi alle direttive e alle norme di seguito menzionate.

Wij verklaren onder onze eigen verantwoordelijkheid dat de volgende producten in overeenstemming zijn met de hieronder genoemde richtlijnen en normen.

Declaramos, bajo nuestra responsabilidad, que los siguientes productos se ajustan a las directivas y las normas mencionadas más abajo.

Declaramos sob nossa exclusiva responsabilidade, que os seguintes produtos estão em conformidade com as diretivas e as normas mencionadas abaixo.

Vi försäkrar på eget ansvar att följande produkter är överensstämmande med nedan angivna direktiv och standarder.

Vi erklærer under eget ansvar, at følgende produkter er i overensstemmelse med nedenstående direktiver og standarder.

Vi erklærer under eneansvar at følgende produkter er i overensstemmelse med direktivene og de standardene som er angitt nedenfor.

Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan yksinomaisella vastuulla. Seuraavassa kuvattut tuotteet ovat mainittujen direktiivien/asetusten ja standardien vaatimusten mukaisia.

Na wyłączną odpowiedzialność producenta oświadcza się, że opisany/-e produkt(y) jest/są zgodny/-e z wymaganiami wymienionych poniżej dyrektyw/rozporządzeń oraz norm.

Na vlastní odpovědnost prohlašujeme, že následující produkty splňují požadavky níže uvedených směrnic/nařízení a norem.

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Product(s):

(Produkt(e) / Produit(s) / Prodotto(i) / Product(en) / Producto(s) / Produto(s) / Produkt(er) / Produkt(er) / Produkt(er)
 / Tuote(Tuotteet)/ Produkt(y))

Article No.	Product Model	Serial No.
101043986	Freestyle pump unit	n/a
101044157	Freestyle Hands-free (DE NL FR IT, EU Plug)	all serial no.
101044158	Freestyle Hands-free (EN, AUS Plug)	all serial no.
101044187	Freestyle Hands-free (EN, UK Plug)	all serial no.
101044159	Freestyle Hands-free (EN ES PT SV, EU Plug)	all serial no.
101044160	Freestyle Hands-free (EN PL, EU Plug)	all serial no.

Applicable directives/regulations:

(Anwendbare Richtlinien/Vorschriften / Directives/réglementations applicables / Direttive/regolamenti applicabili /
 Toepasselijke richtlijnen/verordeningen / Directivas/normativas aplicables / Diretivas/regulamentos aplicáveis /
 Tillämpliga standarder/förordningar / Gældende direktiver/regulativer / Gjældende direktiver/reguleringer /
 Sovellettavat direktiivit/asetukset / Odnośne dyrektywy/rozporządzenia / Platné směrnicе / nařizení)

Reference	Directives/Regulations
2014/35/EU	Directive regarding making available on the market of electrical equipment designed for use within certain voltage limits, known as Low Voltage Directive (LVD)
2014/30/EU	Directive relating to electromagnetic compatibility, known as Electromagnetic Compatibility (EMC) Directive
2011/65/EU	Restriction of use of certain Hazardous Substances in electrical and electronic equipment Directive (RoHS)
2014/53/EU	Radio Equipment Directive (RED) relating to the making available on the market of radio equipment
2012/19/EU	Waste of Electrical and Electronic Equipment (WEEE) Directive
2006/66/EC	Batteries and accumulators and waste batteries and accumulators Directive
1907/2006/EC	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
DGR	Dangerous Goods Regulation
2001/95/EC	General Product Safety Directive (GPSD)
94/62/EC 2005/20/EC	Packaging and packaging waste Directive

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(EU) 2019/1020	Market surveillance and compliance on products EU Regulation
UK Statutory Instruments 2016 No. 1091	The Electromagnetic Compatibility Regulations 2016
UK Statutory Instruments 2016 No. 1101	The Electrical Equipment (Safety) Regulations 2016
UK Statutory Instruments 2017 No. 1206	The Radio Equipment Regulations
UK Statutory Instruments 2012 No. 3032	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
UK Statutory Instruments 2020 No. 1577	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020

Applied Standards:

(Anwendbare Normen / Normes appliquées / Norme applicabili / Toegepaste normen / Normas aplicadas / Normas aplicadas / Tillämpade standarder / Gældende standarder / Anvendte standarder / Sovelletut standardit / Odnosno normy / Použité normy)

Reference	Name
IEC 60335-1:2010/COR1:2010/COR2:2011/ AMD1:2013/COR1:2014/AMD2:2016/COR1:2016 EN 60335-1:2012 + AC:2014 + A11:2014 + A13:2017 + A1:2019 + A2:2019 + A14:2019	Household and similar electrical appliances - Safety - Part 1: General requirements
EN IEC 63000:2022	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
CISPR 14-1:2016	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission
CISPR 14-2:2015	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard
CISPR 32:2015	Electromagnetic compatibility of multimedia equipment - Emission requirements
IEC 61000-6-3:2006 IEC 61000-6-3:2006/AMD1:2010 EN 61000-6-3:2007+A1:2011	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments
EN 300 328 V2.2.2 (2021)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

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IEC 62233:2005 EN 62233:2009	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
IEC 61000-3-2:2018 (Ed 5) EN 61000-3-2: 2014	Electromagnetic compatibility limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC 61000-3-3:2013 + AMD1:2017 EN 61000-3-3:2013+A1:2019	Electromagnetic compatibility limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 55014-1:2017	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission
EN 55014-2:2015	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard
EN 55032:2015+A11:2020	Electromagnetic compatibility of multimedia equipment. Emission Requirements
EN 50663:2017	Generic standard for assessment of low power electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (10 MHz - 300 GHz)
EN 50566:2017	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body
ETSI EN 301 489-1:2017	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements;
ETSI EN 301 489-17:2017	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
UL 1642	Standard for Lithium Batteries
Transport of dangerous goods UN 38.3 (United Nations)	Lithium Metal and Lithium Ion Batteries
IATA Lithium Battery Guidance Document Transport of Lithium Metal and Lithium Ion Batteries Classification (DGR 3.9.2.6) UN 3481	Lithium Ion Batteries contained in equipment or Lithium Ion Batteries packed with equipment (including lithium ion polymer batteries)
IEC 62133-2:2017+AMD1:2021 EN 62133-2:2017+A1:2021	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications

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IEC 61558-1:2017 EN IEC 61558-1:2019	Safety of transformers, reactors, power supply units and combinations thereof - Part 1: General requirements and tests
Bluetooth Test Case Reference List for Bluetooth Qualification Program: TCRL_Profile_2018-2	Bluetooth Profile Interoperability Bluetooth Test Suite Structure and Test Purposes to test Interoperability
Bluetooth Test Case Reference List for Bluetooth Qualification Program: Core.TCRL.2018-2 Bluetooth Radio Frequency Test Suite Structure and Test Purpose: RF-PHY.TS.5.0.3	Bluetooth RF-PHY Conformance Bluetooth Test Suite Structure and Test Purposes to test Bluetooth Low Energy RF-PHY Layer

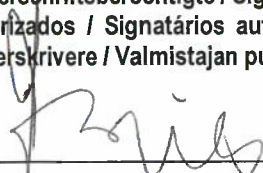
The product(s) is (are) developed and produced under a quality scheme in conformity with ISO 13485.
 Die Produkte werden dem ISO 13485 Qualitätsmanagementsystem entsprechend entwickelt und produziert.
 Les produits sont conçus et fabriqués selon une démarche qualité conforme à la norme ISO 13485.
 I prodotti sono sviluppati e realizzati secondo un sistema di qualità conforme alla norma ISO 13485.
 De producten worden ontwikkeld en geproduceerd in het kader van een kwaliteitsregeling in overeenstemming met ISO 13485.
 Los productos se desarrollan y fabrican siguiendo un programa de calidad conforme con lo establecido en la norma ISO 13485.
 Os produtos são desenvolvidos e produzidos de acordo com um regime de qualidade em conformidade com a ISO 13485.
 Produkterna är utvecklade och tillverkade enligt ett kvalitetsinitiativ i överensstämmelse med ISO 13485.
 Produkterne er udviklet og produceret under en kvalitetsordning i overensstemmelse med ISO 13485.
 Produktene er utviklet og produsert under kvalitetskontroll i samsvar med ISO 13485.
 Tuote(Tuotteet) on (ovat) suunniteltu ja valmistettu ISO 13485 -laatumäärästandardin vaatimusten mukaisesti.
 Produkt(y) jest/są opracowane i wyprodukowane zgodnie z systemem zapewnienia jakości zgodnym z ISO 13485.
 Produkty jsou vyvíjeny a vyráběny v rámci systému kvality v souladu s normou ISO 13485.

This declaration of conformity is valid until: 2025-10-05

(Diese Konformitätserklärung ist gültig bis / Cette déclaration de conformité est valable jusqu'au / La presente dichiarazione di conformità è valida fino al / Deze verklaring van overeenstemming is geldig tot / La presente declaración de conformidad es válida hasta / Esta declaração de conformidade é válida até / Denna deklaration om överensstämmelse gäller till / Denne overensstemmelseserklæring er gyldig indtil / Denne samsvarserklæringen gjelder til / Vaatimustenmukaisuusvakuutuksen voimassaoloaika saakka / Poniższa deklaracja zgodności jest ważna do / Toto prohlášení o shodě platí do)

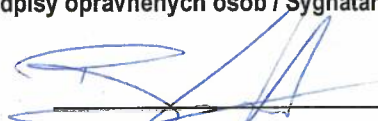
Authorised Signatories:

(Unterschriftsberechtigte / Signataires autorisés / Firmatari autorizzati / Gemachtigde ondertekenaars / Firmantes autorizados / Signatários autorizados / Auktoriserade undertecknare / Autoriserede signatarer / Autoriserte underskrivere / Valmistajan puolesta allekirjoittanut / Podpisy oprávněných osob / Sygnatariusze)



Annette Bruels, CEO

Baar/ Switzerland



Bianca Hedari, Global Senior Director Quality

Baar/ Switzerland

Declaration of Conformity effective from: 2022-10-06