# EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101942
Revision v25

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device(s)/accessories covered by this Declaration are in conformity with all regulations or directives below.

## 1. Object of the declaration:

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|---|---|
| **Product Name:** | DreamStation BiPAP ST<br>DreamStation BiPAP AVAPS |
| **Product Type:** | BiPAP |
| **Intended Purpose:** | BiPAP ST Intended Use Statement:<br><br>The BiPAP S/T device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.<br><br>BiPAP AVAPS Intended Use Statement:<br><br>The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home. |
| **Product Part Number(s) and Descriptions:** | Part Number(s) listed in this section comply with all regulation(s)/directive(s) indicated in DoC unless otherwise noted.<br><br>The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC, Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electric and electronic equipment, amended up to and inclusive of Directive (EU) 2017/1202 (RoHS) in Electric and Electronic Equipment (EEE) and 2014/53/EU Radio Equipment Directive (RED Directive): |

| Part Number | Description |
|---|---|
| **BiPAP AVAPS:** | |
| AUX1131S15 | DreamStation AVAPS30AE AAM AU |
| AUX1131H15 | DreamStation AVAPS30AE AAM w/Humidifier, AU |
| AUX1131T15 | DreamStation AVAPS30AE AAM H/Humid/Heated Tube, AU |
| AUX1131S15C | DreamStation BiPAP AVAPS AVAPS30AE AAM, Cell, AU |
| AUX1131H15C | DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Cell, AU |
| AUX1131T15C | DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Heated Tube/Cell, AU |

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| AUX1131S15W | DreamStation BiPAP AVAPS AVAPS30AE AAM, WiFi, AU |
| AUX1131H15W | DreamStation BiPAP AVAPS AVAPS30AE AAM w/ Humidifier/WiFi, AU |
| AUX1131T15W | DreamStation BiPAP AVAPS AVAPS30AE AAM w/Humidifier/Heated Tube/WiFi, AU |
| BLX1130S15 | DreamStation BiPAP AVAPS30 AAM BL |
| BLX1130H15 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, BL |
| EEX1130S22 | DreamStation BiPAP AVAPS30 AAM EE |
| EEX1130H22 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, EE |
| ESX1130S15 | DreamStation BiPAP AVAPS AVAPS30 AAM, ES |
| ESX1130H15 | DreamStation BiPAP AVAPS AVAPS30, AAM w/ Humidifier, ES |
| EUX1125S15 | DreamStation BiPAP AVAPS AVAPS25, EU |
| EUX1125H15 | DreamStation BiPAP AVAPS AVAPS25, w/Humidifier, EU |
| EUX1130S15 | DreamStation BiPAP AVAPS AVAPS30, AAM, EU |
| EUX1130H15 | DreamStation BiPAP AVAPS AVAPS30, AAM, w/ Humidifier, EU |
| FRX1130S14 | DreamStation BiPAP AVAPS30 AAM FR |
| FRX1130H14 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, FR |
| GBX1130S20 | DreamStation BiPAP AVAPS AVAPS30, GB |
| RGBX1130S20 | DreamStation BiPAP AVAPS30, GB Rental |
| GBX1130H20 | DreamStation BiPAP AVAPS AVAPS30 w/Humidifier, GB |
| ITX1125S21 | DreamStation BiPAP AVAPS25 IT |
| ITX1130S21 | DreamStation BiPAP AVAPS30 IT |
| LDX1130S23 | DreamStation BiPAP AVAPS AVAPS30 AAM, Linde EOLUS 30 DS |
| LDX1130H23 | DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier Linde EOLUS 30 DS |
| MDX1130S25 | DreamStation BiPAP AVAPS AVAPS30 AAM, MedicAir, Respi Comfort AVAPS DS |
| MDX1130H25 | DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier MedicAir, Respi Comfort AVAPS DS |
| NDX1130S15 | DreamStation BiPAP AVAPS30 AAM ND |
| NDX1130H15 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, ND |
| NDX1130S20 | DreamStation BiPAP AVAPS30 ND |
| NDX1130H20 | DreamStation BiPAP AVAPS30 w/Humidifier, ND |
| SAX1130H27 | DreamStation BiPAP Synchrony AVAPS AAM, with Humidifier |
| SAX1130S27 | DreamStation BiPAP Synchrony AVAPS AAM |
| TRX1130S15 | DreamStation BiPAP AVAPS30 AAM TR |
| TRX1130H15 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, TR |
| VTX1130S24 | DreamStation BiPAP AVAPS AVAPS30 AAM, VitalAire, Vitalvent DS |
| VTX1130H24 | DreamStation BiPAP AVAPS AVAPS30 AAM, w/ Humidifier VitalAire, Vitalvent DS |
| SPX1130H21 | DreamStation AVAPS30H – Sapio Belife DS |

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| SPX1130S21 | DreamStation AVAPS30S – Sapio Belife DS |
| BiPAP ST | |
| BLX1030S15 | DreamStation BiPAP ST30 AAM BL |
| BLX1030H15 | DreamStation BiPAP ST30 AAM w/Humidifier, BL |
| DEX1025S13 | DreamStation BiPAP ST25 DE |
| DEX1130S13 | DreamStation BiPAP ST30 AAM DE |
| DEX1130H13 | DreamStation BiPAP ST30 AAM w/Humidifier, DE |
| DEX1030S13 | DreamStation BiPAP ST30 AAM, DE |
| DEX1030H13 | DreamStation BiPAP ST30 AAM w/Humidifier, DE |
| EEX1030S22 | DreamStation BiPAP ST30 EE |
| EEX1030H22 | DreamStation BiPAP ST30 w/Humidifier, EE |
| ESX1030S15 | DreamStation BiPAP S/T ST30 AAM, ES |
| ESX1030H15 | DreamStation BiPAP S/T ST30, AAM w/ Humidifier, ES |
| ESX1030S20 | DreamStation BiPAP S/T ST30, ES |
| ESX1030H20 | DreamStation BiPAP S/T ST30 w/ Humidifier, ES |
| EUX1025S15 | DreamStation BiPAP S/T ST25, EU |
| EUX1025H15 | DreamStation BiPAP S/T ST25, w/ Humidifier, EU |
| EUX1030S15 | DreamStation BiPAP S/T ST30, AAM, EU |
| EUX1030H15 | DreamStation BiPAP S/T ST30, AAM w/ Humidifier, EU |
| FRX1030S14 | DreamStation BiPAP ST30 FR |
| GBX1030S20 | DreamStation BiPAP ST30 GB |
| RGBX1030S20 | Rental, DreamStation ST30, GB |
| GBX1030H20 | DreamStation BiPAP ST30 w/Humidifier, G |
| ITX1030S20 | DreamStation BiPAP S/T ST30, IT |
| ITX1030H20 | DreamStation BiPAP S/T ST30, w/Humidifier, IT |
| NDX1030S15 | DreamStation BiPAP ST30 AAM ND |
| NDX1030H15 | DreamStation BiPAP ST30 AAM w/Humidifier, ND |
| NDX1030S20 | DreamStation BiPAP ST30 ND |
| NDX1030H20 | DreamStation BiPAP ST30 w/Humidifier, ND |
| TRX1030S15 | DreamStation BiPAP ST30 AAM TR |
| TRX1030H15 | DreamStation BiPAP ST30 AAM w/Humidifier, TR |

The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC and Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electric and electronic equipment, amended up to and inclusive of Directive (EU) 2017/1202 (RoHS) in Electric and Electronic Equipment (EEE):

| **Part Number** | **Description** |
|---|---|
| **BiPAP S/T:** | |
| EUX1025S19 | DreamStation BiPAP ST25, no Bluetooth®, EU |
| EUX1025H19 | DreamStation BiPAP ST25 w/ Humidifier, no Bluetooth® EU |
| EUX1030S19 | DreamStation BiPAP ST30 AAM no Bluetooth®, EU |
| EUX1030H19 | DreamStation BiPAP ST30 AAM w/ Humidifier, no Bluetooth® EU |
| INX1025S19 | DreamStation BiPAP ST25 no Bluetooth®, INTL |

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| INX1025H19 | DreamStation BiPAP ST25 w/Humid, no Bluetooth® INTL |
| INX1025T19 | DreamStation BiPAP ST25 w/Humid/Heated Tube, no Bluetooth® INTL |
| INX1030S19 | DreamStation BiPAP ST30 AAM no Bluetooth®, INTL |
| INX1030H19 | DreamStation BiPAP ST30 AAM w/Humid, no Bluetooth® INTL |
| INX1030T19 | DreamStation BiPAP ST30 AAM w/Humid/Heated Tube, no Bluetooth® INTL |
| UAX1030S19 | DreamStation BiPAP ST30 AAM, no Bluetooth®, UA |
| UAX1030H19 | DreamStation BiPAP ST30 AAM w/Humid, No Bluetooth ®, UA |
| ZAX1030S19 | DreamStation BiPAP ST30 AAM no Bluetooth®, ZA |
| ZAX1030H19 | DreamStation BiPAP ST30 AAM w/Humidifier, no Bluetooth® ZA |
| **BiPAP AVAPS:** | |
| EUX1125S19 | DreamStation BiPAP AVAPS25 no Bluetooth®, EU |
| EUX1125H19 | DreamStation BiPAP AVAPS25, w/ Humidifier, no Bluetooth® EU |
| EUX1130S19 | DreamStation BiPAP AVAPS30 AAM, no Bluetooth®, EU |
| EUX1130H19 | DreamStation BiPAP AVAPS30, AAM, w/ Humidifier, no Bluetooth®, EU |
| INX1125S19 | DreamStation BiPAP AVAPS25 no Bluetooth®, INTL |
| INX1125H19 | DreamStation BiPAP AVAPS25 w/Humid, no Bluetooth® INTL |
| INX1125T19 | DreamStation BiPAP AVAPS25 w/Humid/Heated Tube, no Bluetooth® INTL |
| INX1130S19 | DreamStation BiPAP AVAPS30 AAM no Bluetooth®, INTL |
| INX1130H19 | DreamStation BiPAP AVAPS30 AAM w/Humid, no Bluetooth® INTL |
| INX1130T19 | DreamStation BiPAP AVAPS30 AAM w/Humid/Heated Tube, no Bluetooth® INTL |
| INX1131S19 | DreamStation BiPAP AVAPS30AE AAM no Bluetooth®, INTL |
| INX1131H19 | DreamStation BiPAP AVAPS30AE AAM w/Humid, no Bluetooth® INTL |
| INX1131T19 | DreamStation BiPAP AVAPS30AE AAM w/Humid/Heated Tube, no Bluetooth® INTL |
| UAX1130S19 | DreamStation BiPAP AVAPS30 AAM, no Bluetooth®, UA |
| UAX1130H19 | DreamStation BiPAP AVAPS30 AAM w/HUMID, no Bluetooth®, UA |
| ZAX1130S19 | DreamStation BiPAP AVAPS30 AAM no Bluetooth®, ZA |
| ZAX1130H19 | DreamStation BiPAP AVAPS30 AAM w/Humidifier, no Bluetooth® ZA |

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| **Product Options/Accessories Part Number(s) and Descriptions**: | The below optional accessories are used in combination with the medical device(s) that are on this DoC, but are CE marked on its own and subject to their own DoC. Being CE marked on their own, they are mentioned here for reference only and will not be considered any further in this DoC. Hence, the accessories product name(s) listed below are NOT included in this DoC.<br><br>Refer to REG 2101599 (humidifiers), REG 2101588 (connectivity), REG 2101640 (SpO2), REG 2101724 (power cords/adaptors) |
| **Basic UDI-DI:** | N/A |

**Control Indicator:**

| Initial Issue Date: | Part Number: |
|---|---|
| Nov. 21, 2016 | FRX1130S14, AUX1131S15, AUX1131H15, AUX1131T15, INX1025S19, INX1025H19, INX1025T19, INX1030S19, INX1030H19, INX1030T19, INX1125S19, INX1125H19, INX1125T19, INX1130S19, INX1130H19, INX1130T19, INX1131S19, INX1131H19, INX1131T19, GB11100135, IN1120135, EU1120135 |
| Jan. 12, 2017 | BLX1030H15, BLX1030S15, BLX1130H15, BLX1130S15, DEX1025S13, DEX1130H13, DEX1130S13, EEX1030H22, EEX1030S22, EEX1130H22,EEX1130S22, ESX1030H15, ESX1030S15, ESX1130H15, ESX1130S15, EUX1025H15, EUX1025S15, EUX1030H15, EUX1030S15, EUX1125H15, EUX1125S15, EUX1130H15, EUX1130S15, EUX1025H19, EUX1025S19, EUX1030H19, EUX1030S19, EUX1125H19, EUX1125S19, EUX1130H19,EUX1130S19, FRX1030S14, FRX1130H14, GBX1030H20, GBX1030S20, ITX1125S21, ITX1130S21,NDX1030H15, NDX1030H20, NDX1030S15, NDX1030S20, NDX1130H15, NDX1130H20, NDX1130S15, NDX1130S20, TRX1030H15, TRX1030S15, TRX1130H15, TRX1130S15, ZAX1030S19, ZAX1030H19, ZAX1130S19, ZAX1130H19 |
| Jan. 26, 2017 | AUX1131S15C, AUX1131H15C, AUX1131T15C AUX1131S15W, AUX1131H15W, AUX1131T15W |
| Aug. 23, 2017 | ESX1030S20, ESX1030H20, GBX1130S20, GBX1130H20 |
| Dec. 14, 2017 | LDX1130S23, LDX1130H23, MDX1130S25, MDX1130H25, SAX1130S27, SAX1130H27, VTX1130S24, VTX1130H24 |
| Apr. 3, 2018 | ITX1030S20, ITX1030H20 |
| Sep 18, 2019 | SPX1130H21, SPX1130S21 |
| Oct. 24, 2018 | RGBX1030S20, RGBX1130S20 |
| Jul. 8, 2020 | DEX1030S13, DEX1030H13 |

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| | <table><tr><td>Jun. 24, 2020</td><td>UAX1030H19, UAX1030S19, UAX1130H19, UAX1130S19</td></tr></table><br>For RED Directive:<br><table><tr><th>Serial Range</th><th>Software Version</th></tr><tr><td>J193962212669 and higher</td><td>1.0 and higher</td></tr></table><br>*Note: Devices manufactured in compliance with R&TTE are outside of the serial number range but are deemed RED compliant as no hardware or software changes were required to demonstrate compliance to the Radio Equipment Directive.* |
| **Global Medical Device Nomenclature code (GMDN) and Description** | 47083 Portable electric ventilator |

The object of the Declaration (product part numbers and if applicable the component part numbers) that are described above as included in this DoC is / are in conformity with the following regulations / directives. If optional accessories that are used in combination with the product (medical device), but are CE marked on their own are referenced in this DoC, they are excluded further on as these optional accessories have their own DoC.

| **EU Directive** | **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)** |
|---|---|
| **Risk Classification** | Class IIb based on Annex IX and Rule 9 |
| **Conformity Assessment Route** | Annex II excluding 4 |
| **Notified Body Name, Address, and ID** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 München, Germany<br>Notified Body no. 0123 |
| **Certificate(s) Issued** | G1 015581 0611 |
| **Standards** | The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below.<br><br>Refer to Attachment A. |

From July 22, 2021 onward, product is to be compliant up through Directive 2015/683 (RoHS 3) as amended up to 2017/2102 and the following table is to be used related to RoHS compliance once product has been verified as compliant.

| **EU Directive** | **Directive 2015/863 of the European Parliament and of the Council of 8 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102** |
|---|---|
| **Risk Classification** | Category 8, medical device, according Annex I. |
| **Standards** | The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below.<br><br>*Refer to Attachment A.* |

| **EU Directive** | ***Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED)*** |
|---|---|
| **Risk Classification** | Class 1 |
| **Conformity Assessment Route** | Annex III |
| **Notified Body Name, Address, ID and EU Certificate Number** | The Notified Body identified in this section performed EU Type Examination and issued the certificate<br><br>Intertek Testing & Certification Ltd.<br>Cleeve Road, Leatherhead, Surrey, KT22 7SB<br>United Kingdom<br>Notified Body Number: 0359<br>Certificate Number: 0002324, 0005392 |
| **Standards** | The radio equipment was tested to the following standards or technical specifications:<br><br>Refer to Attachment A |

## 2. Mandatory information:

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|---|---|
| **Manufacturer** | Respironics, Inc.<br>1001 Murry Ridge Lane<br>Murrysville, PA 15668 USA |
| **EU Authorized Representative (AR):** | Respironics Deutschland GmbH & Co. KG<br>Gewerbestrasse 17<br>82211 Herrsching, Germany<br>Tel: +49 8152 93060 |
| **ISO Quality Certificates Issued:** | The Manufacturer is certified by TUV to the following:<br><br>EN ISO 13485 and Annex II-Section 3.2 of the MDD as evidenced by certificate numbers:<br><br>EN ISO 13485:2016: Q5 015581 0609<br>MDSAP ISO 13485:2016: QS6 112601 0001 |

Signature (signed for and on behalf of) Respironics, Inc.:

Daria Brown

Date of Issue: 08 September 2021

Sept 08, 2021

Printed Name: Daria Brown

Place of Issue: Pittsburgh, PA, USA

Title: Sr. Manager, Regulatory Affairs

### 3. Attachment A Standards and/or Common Specifications

| Standard | Standard Title |
|---|---|
| **Quality System** | |
| EN ISO 13485:2016 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| **General Safety Standard** | |
| EN 60601-1:2006/A1:2013 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **Collateral Safety Standards** | |
| EN 60601-1-2:2014 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility. Requirements and tests |
| EN 60601-1-6:2010/ A1:2015 | Medical electrical equipment – Part 1-6: General requirements for safety and essential performance – Collateral standard: Usability |
| EN 60601-1-8:2007/ A11:2017 | Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| EN 60601-1-11:2015 | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| **Particular Safety Standards** | |
| **Humidifiers** | |
| EN ISO 80601-2-74:2020 | Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment |
| **Home Care Ventilators** | |
| ISO 80601-2-79:2018 | Medical electrical equipment – Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment |
| **Anaesthetic and Respiratory Equipment** | |
| EN ISO 5356-1:2015 | Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets |
| **Biocompatibility** | |
| EN ISO 10993-1:2020 | Biological evaluation of medical devices – Part 1: Evaluation and testing |
| EN ISO 10993-3:2014 | Biological evaluation of medical devices–Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity |
| EN ISO 10993-5:2009 | Biological evaluation of medical devices–Part 5: Tests for in vitro cytotoxicity |
| ISO 10993-10:2010 | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization |

| Standard | Standard Title |
|---|---|
| EN ISO 10993-17:2009 | Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances |
| EN ISO 10993-18:2020 | Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process |
| EN ISO 18562-1:2020 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process |
| EN ISO 18562-2:2020 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter |
| EN ISO 18562-3:2020 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds |
| EN ISO 18562-4:2020 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate |
| **Pulse Oximetry** | |
| EN ISO 80601-2-61:2019 | Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment |
| **Other Standards** | |
| **Accompany Documents and Labeling** | |
| EN 1041:2008/A1:2013 | Information supplied by the manufacturer of medical devices |
| EN ISO 15223-1: 2017 | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| **Software** | |
| EN 62304:2006/A1:2015 | Medical device software – Software lifecycle processes |
| **Risk Management** | |
| EN ISO 14971:2019 | Medical devices – Application of risk management to medical devices |
| **Usability** | |
| EN 62366-1:2015/ AC:2015 | Medical devices – Part 1: Application of usability engineering to medical devices |
| **Radio** | |
| EN 62311:2008 | Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz) |
| EN 60950-1:2005 A1:2009/ A2:2013 | Information technology equipment. Safety. Part 1: General requirements |
| EN 55032:2015 | Electromagnetic compatibility of multimedia equipment - Emission Requirements |
| EN 301 908 -1 V11.1.1:2016 | IMT cellular networks; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 1: Introduction and common requirements |

| Standard | Standard Title |
|---|---|
| EN 301 908-2 V11.1.1:2016 | IMT cellular networks; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU; Part 2: CDMA Direct Spread (UTRA FDD) User Equipment (UE) |
| EN 300 328 V2.1.1:2016 | Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques |
| EN 301 489-1 V2.1.1:2017 | ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU |
| EN 301 489-17 V3.1.1:2017 | ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU EMC for broadband data transmission systems |
| EN 301 489-52 V1.1.0:2016 | Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 52: Specific conditions for Cellular Communication Mobile and portable (UE) radio and ancillary equipment; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU |
| EN 301 511 V12.5.1:2016 | Global System for Mobile communications (GSM); Mobile Stations (MS) equipment; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU |
| **RoHS** | |
| EN IEC 63000:2018 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| **Cleaning and Disinfection** | |
| EN ISO 17664:2017 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices |