EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101545
Revision v40

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:

Product Name:	DreamStation CPAP DreamStation CPAP Pro DreamStation Auto CPAP DreamStation Expert DreamStation BiPAP Pro DreamStation Auto BiPAP DreamStation Travel Kit DreamStation Flow Generator Cover DreamStation Micro-Flex PR12 Tube Starter Pack
Product Type:	Non-continuous ventilator
Intended Purpose:	For the treatment of Obstructive Sleep Apnea (OSA)
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directive(s) indicated in DoC unless otherwise noted. 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) 2017/2102 (RoHS) in Electric and Electronic Equipment (EEE) and 2014/53/EU Radio Equipment Directive (RED Directive): ARX200S15 DreamStation CPAP, AR ARX200H15 DreamStation CPAP w/Humid, AR ARX200H15C DreamStation CPAP w/Hum/Cell, AR ARX401S15 DreamStation CPAP Pro, AR ARX401H15 DreamStation CPAP Pro w/Humid, AR ARX401H15C DreamStation CPAP Pro w/Hum/Cell, AR ARX500S15 DreamStation Auto CPAP, AR ARX500H15 DreamStation Auto CPAP w/Humid, AR ARX500H15C DreamStation Auto CPAP w/Hum/Cell, AR ARX600S15 DreamStation BiPAP Pro, AR ARX600S15C DreamStation BiPAP Pro w/Cell, AR ARX600H15 DreamStation BiPAP Pro w/Humid, AR ARX700S15 DreamStation Auto BiPAP, AR ARX700S15C DreamStation Auto BiPAP w/Cell, AR ARX700H15 DreamStation Auto BiPAP w/Humid, AR

AUX400S15	DreamStation CPAP Pro, AUS
AUX500S15	DreamStation Auto CPAP, AUS
AUX700S15	DreamStation Auto BiPAP, AUS
AUX400H15	DreamStation CPAP Pro w/Humid, AUS
AUX500H15	DreamStation Auto CPAP w/Humid, AUS
AUX700H15	DreamStation Auto BiPAP w/Humid, AUS
AUX400T15	DreamStation CPAP Pro w/Humid/HT, AUS
AUX500T15	DreamStation Auto CPAP w/Humid/HT, AUS
AUX700T15	DreamStation Auto BiPAP w/Humid/HT, AUS
AUX400T15C	DreamStation CPAP Pro w/Humid/HT/Cell, AUS
AUX500T15C	DreamStation Auto CPAP w/Humid/HT/Cell, AUS
AUX700T15C	DreamStation Auto BiPAP w/Humid/HT/Cell, AUS
BLX200S15	DreamStation CPAP BL
BLX200H15	DreamStation CPAP with Humidifier BL
BLX400S15	DreamStation CPAP Pro BL
BLX400H15	DreamStation CPAP Pro with Humidifier BL
BLX500S15	DreamStation Auto CPAP BL
BLX500H15	DreamStation Auto CPAP with Humidifier BL
BLX600S15	DreamStation BiPAP Pro BL
BLX700S15	DreamStation Auto BiPAP BL
BLX700H15	DreamStation Auto BiPAP with Humidifier BL
BLX400H15C	DreamStation CPAP Pro w/Hum/Cell, BL
BLX500H15C	DreamStation Auto CPAP w/Hum/Cell, BL
BLX400S15C	DreamStation CPAP Pro w/Cell, BL
BLX500S15C	DreamStation Auto CPAP w/Cell, BL
BLX201S15	DreamStation CPAP w/AHI, BL
BLX201S15C	DreamStation CPAP w/AHI/Cell, BL
BLX500H15MQ	DreamStation Auto CPAP w/Humid, Mediq
DEX400S13	DreamStation CPAP Pro GER
DEX500S13	DreamStation Auto CPAP GER
DEX700S13	DreamStation Auto BiPAP GER
EEX400S15	DreamStation CPAP Pro EE
EEX400H15	DreamStation CPAP Pro with Humidifier EE
EEX500S15	DreamStation Auto CPAP EE
EEX500H15	DreamStation Auto CPAP with Humidifier EE
EEX700S15	DreamStation Auto BiPAP EE
EEX700H15	DreamStation Auto BiPAP with Humidifier EE
ESX200S15	DreamStation CPAP ES
ESX400S15	DreamStation CPAP Pro ES
ESX500S15	DreamStation Auto CPAP ES
ESX700S15	DreamStation Auto BiPAP ES
ESX400H15	DreamStation CPAP Pro with Humidifier ES

	ESX500H15	DreamStation Auto CPAP with Humidifier ES
	ESX700H15	DreamStation Auto BiPAP with Humidifier ES
	ESX401H15	DreamStation CPAP Pro w/Humid, ES
	ESX401S15	DreamStation CPAP Pro, ES
	ESX401S15C	DreamStation CPAP Pro w/Cell, ES
	ESX401H15C	DreamStation CPAP Pro w/Hum/Cell, ES
	ESX500S15C	DreamStation Auto CPAP w/Cell, ES
	ESX500H15C	DreamStation Auto CPAP w/Hum/Cell, ES
	ESX201S15	DreamStation CPAP w/AHI, ES
	ESX201S15C	DreamStation CPAP w/AHI/Cell, ES
	EUX200S15	DreamStation CPAP EU
	EUX200H15	DreamStation CPAP with Humidifier EU
	EUX400S15	DreamStation CPAP Pro EU
	EUX401S15	DreamStation CPAP Pro w/ Auto-Trial, EU
	EUX400H15	DreamStation CPAP Pro with Humidifier EU
	EUX401H15	DreamStation CPAP Pro w/A-Trial/Hum, EU
	EUX500S15	DreamStation Auto CPAP EU
	EUX500H15	DreamStation Auto CPAP with Humidifier EU
	EUX600S15	DreamStation BiPAP Pro EU
	EUX600H15	DreamStation BiPAP Pro with Humidifier EU
	EUX700S15	DreamStation Auto BiPAP EU
	EUX700H15	DreamStation Auto BiPAP with Humidifier EU
	FRX400S14	DreamStation Pro FR
	FRX500S14	DreamStation Auto FR
	FRX501S14	DreamStation Expert FR
	FRX700S14	DreamStation BiPAP Auto FR
	FRX500S14W	DreamStation Auto w/WiFi, FR
	FRX501H14W	DreamStation Expert w/Humidifier/WiFi, FR
	GBX400H15	DreamStation CPAP Pro with Humidifier GB
	GBX400S15	DreamStation CPAP Pro GB
	GBX500H15	DreamStation Auto CPAP with Humidifier GB
	GBX500S15	DreamStation Auto CPAP GB
	GBX700H15	DreamStation Auto BiPAP with Humidifier GB
	GBX700S15	DreamStation Auto BiPAP GB
	GBX401H15	DreamStation CPAP Pro w/Humid, GB
	GBX401S15	DreamStation CPAP Pro, GB
	INX200H15	DreamStation CPAP w/Humid, INTL
	INX200S15	DreamStation CPAP, INTL
	INX200T15	DreamStation CPAP w/Humid/HT, INTL
	INX400H15	DreamStation CPAP Pro w/Humid, INTL
	INX400S15	DreamStation CPAP Pro, INTL
	INX400T15	DreamStation CPAP Pro w/Humid/HT, INTL
	INX500H15	DreamStation Auto CPAP w/Humid, INTL
	INX500S15	DreamStation Auto CPAP, INTL
	INX500T15	DreamStation Auto CPAP w/Humid/HT, INTL

	INX600H15	DreamStation BiPAP Pro w/Humid, INTL
	INX600S15	DreamStation BiPAP Pro, INTL
	INX600T15	DreamStation BiPAP Pro w/Humid/HT, INTL
	INX700H15	DreamStation Auto BiPAP w/Humid, INTL
	INX700S15	DreamStation Auto BiPAP, INTL
	INX700T15	DreamStation Auto BiPAP w/Humid/HT, INTL
	ITX200S15	DreamStation CPAP IT
	ITX400S15	DreamStation CPAP Pro IT
	ITX500S15	DreamStation Auto CPAP IT
	ITX700S15	DreamStation Auto BiPAP IT
	ITX400H15W	DreamStation CPAP Pro w/Humid/WiFi, IT
	ITX500H15W	DreamStation Auto CPAP w/Humid/WiFI, IT
	NDX500S15	DreamStation Auto CPAP ND
	NDX500H15	DreamStation Auto CPAP with Humidifier ND
	NDX700S15	DreamStation Auto BiPAP ND
	NDX700H15	DreamStation Auto BiPAP with Humidifier ND
	NDX500S15C	DreamStation Auto CPAP w/Cell, ND
	NDX500H15C	DreamStation Auto CPAP w/Hum/Cell, ND
	PTX500H15PR	DreamStation Auto CPAP Praxair with Humidifier Portugal
	PTX500H15PRW	DreamStation Auto CPAP Praxair with Humidifier/ WiFi Portugal
	PTX500H15PRC	DreamStation Auto CPAP Praxair with Humidifier/ Cell Portugal
	PWX401H15	DreamStation CPAP Pro w/Humid, PW, 22mm
	PWX401S15	DreamStation CPAP Pro, PW, 22mm
	TRX200S15	DreamStation CPAP TR
	TRX200H15	DreamStation CPAP with Humidifier TR
	TRX400S15	DreamStation CPAP Pro TR
	TRX400H15	DreamStation CPAP Pro with Humidifier TR
	TRX500S15	DreamStation Auto CPAP TR
	TRX500H15	DreamStation Auto CPAP with Humidifier TR
	TRX600H15	DreamStation BiPAP Pro with Humidifier TR
	TRX700H15	DreamStation Auto BiPAP with Humidifier TR
	LAX200S15	DreamStation CPAP, LA
	LAX200H15	DreamStation CPAP w/ Humid, LA
	LAX200H15C	DreamStation CPAP w/Hum/Cell, LA
	LAX200T15	DreamStation CPAP w/ Humid/HT, LA
	LAX400S15	DreamStation CPAP Pro, LA
	LAX400H15	DreamStation CPAP Pro w/ Humid, LA
	LAX400H15C	DreamStation CPAP Pro w/Hum/Cell, LA

	LAX400T15 DreamStation CPAP w/ Humid/HT, LA LAX500S15 DreamStation Auto CPAP, LA LAX500H15 DreamStation Auto CPAP w/ Humid, LA LAX500H15C DreamStation Auto CPAP w/Hum/Cell, LA LAX500T15 DreamStation CPAP w/ Humid/HT, LA LAX600S15 DreamStation BiPAP Pro, LA LAX600H15 DreamStation BiPAP Pro w/ Humid, LA LAX600H15C DreamStation BiPAP Pro w/Hum/Cell, LA LAX600T15 DreamStation CPAP w/ Humid/HT, LA LAX700S15 DreamStation Auto BiPAP, LA LAX700H15 DreamStation Auto BiPAP w/ Humid, LA LAX700H15C DreamStation Auto BiPAP w/Hum/Cell, LA LAX700T15 DreamStation CPAP w/ Humid/HT, LA RGBX500H15 DreamStation Auto CPAP w/Humid, GB Rent RGBX500S15 DreamStation Auto CPAP, GB Rental RGBX700S15 DreamStation Auto BiPAP, GB Rental RDEX400S13 DreamStation REMstar Pro Rental RDEX500S13 DreamStation REMstar Auto Rental RDEX700S13 DreamStation BiPAP Auto Rental UFRX500S14 DreamStation Auto FR Recert UAX400S15 DreamStation CPAP Pro, Ukraine UAX500S15 DreamStation Auto CPAP, Ukraine UAX700S15 DreamStation Auto BiPAP, Ukraine AU1120135 DreamStation Travel Kit, 65W P/S, AU IN1120135 DreamStation Travel Kit, 65W P/S, IN EU1120135 DreamStation Travel Kit, 65W P/S, EU 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) 2017/2102 (RoHS) in Electric and Electronic Equipment (EEE): 1128163 DreamStation Flow Generator Cover 1128071 DreamStation Micro-Flex PR12 Tube Starter Pack
Product Options/Accessories Part Number(s) and Descriptions:	Refer to REG 2101724 for the DreamStation Power Accessories and REG 2102976 for the Universal Battery Pack and REG 2101640 for Nonin Spo2 Cable
Basic UDI-DI:	N/A

Control Indicator:	Initial Issue Date:	Part Number(s):
	July 15, 2015	AUX400S15, AUX500S15, AUX700S15, AUX400H15, AUX500H15, AUX700H15, AUX400T15, AUX500T15, AUX700T15, DEX400S13, DEX500S13, DEX700S13
	July 17, 2015	ESX200S15, ESX400S15, ESX500S15, ESX700S15, ESX400H15, ESX500H15, ESX700H15
	Sept. 11, 2015	FRX400S14, FRX500S14, FRX501S14, FRX700S14, GBX400H15, GBX400S15, GBX500H15, GBX500S15, GBX700H15, GBX700S15
	Sept.29, 2015	INX200H15, INX400H15, INX500H15, INX600H15, INX700H15, INX200S15, INX400S15, INX500S15, INX600S15, INX700S15, INX200T15, INX400T15, INX500T15, INX600T15, INX700T15
	Nov. 05, 2015	BLX200S15, BLX200H15, BLX400S15, BLX400H15, BLX500S15, BLX500H15, EEX400S15, EEX400H15, EEX500S15, EEX500H15, EUX200S15, EUX200H15, EUX400S15, EUX400H15, EUX500S15, EUX500H15, ITX200S15, ITX400S15, ITX500S15, NDX500S15, NDX500H15, NDX700H15, NDX700S15, TRX200S15, TRX200H15, TRX400S15, TRX400H15, TRX500S15, TRX500H15,
	Dec. 21, 2015	BLX600S15, BLX700S15, BLX700H15, EEX700S15, EEX700H15, EUX600S15, EUX600H15, EUX700S15, EUX700H15, ITX700S15, TRX600H15, TRX700H15
	March 09, 2016	ITX400H15W, ITX500H15W
	March 16, 2016	AU1120135, IN1120135, EU1120135
	July 19, 2016	AUX400T15C, AUX500T15C
	Sept. 7, 2016	AUX700T15C
	October 13, 2016	1128163

	October 26, 2016	LAX200S15, LAX200H15, LAX200T15, LAX400S15, LAX400H15, LAX400T15, LAX500S15, LAX500H15, LAX500T15, LAX600S15, LAX600H15, LAX600T15, LAX700S15, LAX700H15, LAX700T15
	Nov. 29, 2016	ESX401H15, ESX401S15, GBX401H15, GBX401S15
	Dec. 06, 2016	1128071
	July 6, 2017	FRX500S14W
	July 18, 2017	ARX200S15, ARX200H15, ARX401S15, ARX401H15, ARX500S15, ARX500H15, ARX600S15, ARX600H15, ARX700S15, ARX700H15
	Sept. 06, 2017	KRX200H15, KRX200S15, KRX200T15, KRX400H15, KRX400S15, KRX400T15, KRX500H15, KRX500S15, KRX500T15, KRX600H15, KRX600S15, KRX600T15, KRX700H15, KRX700S15, KRX700T15
	Dec. 5, 2017	PTX500H15PR
	March 12, 2018	PTX500H15PRW, PTX500H15PRC, FRX501H14W
	July 16, 2018	EUX401H15, EUX401S15
	Feb. 18, 2019	PWX401H15, PWX401S15
	April 19, 2016	RGBX500H15, RGBX500S15
	March 30, 2017	RDEX400S13, RDEX500S13, RDEX700S13
	Sept. 1, 2017	UFRX500S14
	July 7, 2020	UAX400S15, UAX500S15, UAX700S15
	Aug 17, 2020	ESX401S15C, ESX401H15C, ESX500S15C, ESX500H15C, NDX500S15C, NDX500H15C, BLX400H15C, BLX500H15C, BLX400S15C, BLX500S15C
	Sep 16, 2020	BLX201S15, BLX201S15C, ESX201S15, ESX201S15C

	Sept. 22, 2020 BLX500H15MQ Jan. 29, 2021 ARX200H15C, ARX401H15C, ARX500H15C, ARX600S15C, ARX700S15C, LAX200H15C, LAX400H15C, LAX500H15C, LAX600H15C, LAX700H15C March 26,2021 RGBX700S15 ********** For RED Directive: **Serial Range** / **Software Version** J18858389660F and higher / 1.1 and higher *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	60711 Home CPAP Unit 60712 Home BiPAP Unit

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 IIa 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 Ridlerstrasse 65 80339 München, Germany 0123

Certificate(s) Issued	No. 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. *Refer to Attachment A.*

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 to 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. 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 I
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. Intertek Testing & Certification Ltd. Cleve Road, Leatherhead, Surrey, KT22 7SB United Kingdom Notified Body Number: 0359 Certificate Numbers 0002325, 0002326, 0005391
Standards	The radio equipment was tested to the following standards or technical specifications: Refer to Attachment A

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RESPIRONICS®

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2. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 USA
EU Authorized Representative (AR):	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485 Certificate: Q5 015581 0609 MDSAP ISO 13485 Certificate: QS6 112601 0001

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

Date of Issue: 15-SEP-2021

Printed Name: Katelyn Manning

Place of Issue: Pittsburg, PA

Title: Sr. Manager, Regulatory Affairs

3. Attachment A Standards and/or Common Specifications

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 60601-1-2:2015	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 60601-1-11:2015	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.
Sleep Apnea Devices	
ISO 80601-2-70:2015	Medical Electrical Equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
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
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
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 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
Anaesthetic and Respiratory Equipment	
EN ISO 5356-1: 2015	Anaesthetic and Respiratory Equipment: Conical Connectors – Part 1: Cones and Sockets
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
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