ETEC Desktop Health

CE

EU Declaration of Conformity

MANUFACTURER

EnvisionTEC GmbH
Bruesseler Str. 51
45968 Gladbeck
Germany

MODELS

Einstein Pro XL™ and Pro XL™

DESCRIPTION

Product: Einstein Pro XL and Pro XL Printers use a 3D printing process to create objects from various polymeric materials. Desktop Health and ETEC are brand names owned by Desktop Metal Inc or its affiliated companies.

The undersigned hereby declares, on behalf of EnvisionTEC GmbH, that the above-referenced products, to which this declaration relates, is in conformity with the provisions of:

Council Directive 2014/53/EU on Radio Equipment.

- Harmonized Standards used:
- EN 301 489-1 V2.2.3 (2019-11); Electro Magnetic 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 V3.2.4 (2020-09); Electro Magnetic 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.
- EN 300 328 V2.2.2; 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.
- EN 301 893 V2.1.1; 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- EN 300 330 V2.1.1 (2017-02) Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU.
- ETSI EN 300 440 V2.1.1: Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Council Directive 2006/42/EC on Machinery Directive / Council Directive 2014/35/EU Low Voltage Directive.

- EN 62368-1:2014 / AC2015; Information and communication technology equipment – Part 1: Safety requirements.
- EN ISO 12100:2010 – Safety of machinery – General Principles for design – Risk assessment and risk reduction.
- EN 62479:2010 - Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

Council Directive 2014/30/EU EMC Directive.

- EN 55035:2017/A11:2022: Electromagnetic Compatibility of Multimedia Equipment – Immunity Requirements.
- EN 55024:2010: Information technology equipment - Immunity characteristics - Limits and methods of measurement.
- EN 55032:2015 +AC:2016: Electromagnetic compatibility of multimedia equipment - Emission Requirements
- EN 61000-3-2:2014: Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).

- EN 61000-3-3:2013: Electromagnetic compatibility (EMC) - Part 3-3: 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 61000-4-2:2009; IEC 61000-4-2:2008 ED2.0: Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- EN 61000-4-3:2006 +A1:2008 +A2.-2010; IEC 61000-4-3:2010 ED. 3.2: Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test.
- EN 61000-4-4:2012; IEC 61000-4-4:2012 ED. 3.0: Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test.
- EN 61000-4-5:2014 +A1:2017; IEC 61000-4-5:2017 ED. 3.1: Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test.
- EN 61000-4-6:2014; IEC 61000-4-6:2013 ED. 4.0: Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields.
- EN 61000-4-8:2010; IEC 61000-4-8:2009 ED. 2.0: Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test.
- EN 61000-4-11:2004 +A1: 2017 IEC 61000-4-11:2017 ED. 2.1: Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase.

Council Directive 2011/65/EU on Restriction of Hazardous Substances in Electrical and Electronic Equipment.

- EN 63000:2018; Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

The Technical Construction File required by these Directives is maintained at the corporate headquarters of EnvisionTEC GmbH, Bruesseler Str. 5145968 Gladbeck, Germany.

EU Authorized Representative

	EnvisionTEC GmbH
Ruediger Van Bernum	Bruesseler Str. 51
Operations Manager	45968 Gladbeck
	Germany
Print Name (First, Last) / Title	Address
ppa. R. van Bernum	2023-11-28
Signature	Date (YYYY/MM/DD)

Person empowered to draw up the declaration

	Desktop Metal Operating Inc
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	USA
Print Name (First, Last) / Title	Address
	2023-11-28
Signature	Date (YYYY/MM/DD)