



Declaration of Conformity

We, Discus Dental, LLC.
(Company name)

1700A South Baker Avenue, Ontario, CA 91761, USA
(address)

Declare under our responsibility that the product(s):

Product Description	Model No	SKU
Tooth Whitening Accelerator Light	ZME3000	881057700020
		881024200300
		881024202160

Philips Zoom! WhiteSpeed LED Accelerator
(Brand name)

To which this declaration relates is in conformity with the following EU Directives:

- Directive 2001/95/EC - General Product Safety
- Directive 2014/35/EU – Low Voltage Directive (LVD)
- Directive 2014/30/EU – Electromagnetic compatibility (EMC)
- Directive 2012/19/EU – WEEE
- Directive 94/62/EC - Packaging and Packaging Waste Directive
- Directive 2011/65/EU & Directive 2015/863/EU - Restriction of the use of certain hazardous substances (RoHS)
- Regulation 1907/2006 – Chemical Substances (REACH)

Name: Sanjay J. Patel

Title: Dir., Q&R, Quality Products Manufacturing

Signature: 

Date: 14-AUG-2025

2021-07

(Year, Month in which the CE mark is affixed)



Standards:

EN 60601-1-2:2014 Ed. 4, Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

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 \leq 16 A per phase and not subject to conditional connection

EN 61000-4-2:2008, Electromagnetic compatibility (EMC) Testing and measurement techniques. Electrostatic discharge immunity test

EN 61000-4-3 Ed3.0 + A1 +A2, Electromagnetic compatibility (EMC) Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test

EN 61000-4-4:2012, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

EN 61000-4-5:2014, Electromagnetic compatibility (EMC) Testing and measurement techniques. Surge immunity test

EN 61000-4-6: Ed2.0 +A1+A2, Electromagnetic compatibility (EMC) Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields

EN 61000-4-8:2009, Electromagnetic compatibility (EMC) Testing and measurement techniques. Power frequency magnetic field immunity test

- EN 61000-4-11:2004
- IEC 63000:2018
- IEC 80601-2-60 (1st Ed.): 2012
- IEC 62471:2006
- IEC 60601-1:2005+ CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-1-6:2010, AMD1:2013
- IEC 60601-2-57: 2011
- EN 13427:2004