3DISC

Declaration of Conformity

Legal Manufacturer:	3DISC Americas 365 Herndon Pkwy #18 Herndon, VA 20170, USA
Tel:	+ 1 703 430 6080
Product:	Optical Intraoral Scanner
Model Name:	Heron IOS
Device Classification:	Class 1, Rule 12 according to Annex IX of the MDD 93/42/EEC
GMDN Code and Term:	63669 Intraoral optical scanning system
European Representative:	3DISC Dental Connect 10-12, rue de l'Amiral Hamelin 75116 Paris, France
Tel:	+ 33 (0)1-42-25-73-98

We, the legal manufacturer under our sole responsibility hereby declare, that the above mentioned product complies with the Medical Devices Directive 93/42/EEC (as amended by Directive 2007/47/EC), RoHS2 Directive 2011/65/EU, Waste Electrical and Electronic Equipment Directive (WEEE) 2012/19/EU and its relevant transposition into national laws of the member states into which we place the device. The following reference standards were applied in part or in full to the manufacturing of the device:

- EN ISO 14971:2019
- EN 60601-1 (2005)
- EN 60601-1-2 (2014)
- EN 62471:2008
- EN ISO 10993-1 (2018)
- EN 62304: 2006
- ISO 13485:2016 (Certificate No. 0097208 issued by Intertek)
- EN ISO 15223-1:2021
- EN ISO 17665-1:2006

Name: Walter Galvez (Quality/Regulatory Manager)

Date: 30-JUL-2021

Signature:

Place: 365 Herndon Pkwy #18, Herndon, VA 20170, USA

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