


CONFORMITY INFORMATION		
1.	Name of Issuer	VOXELTEK Ltd.
2.	Address of the Issuer	5-7 Dorogi Road H-2509 Esztergom-Kertvaros, Hungary
3.	Technology supervisor for Issuer	Marton Bartos
4.	Address of the technology supervisor	3 Hunyadi Janos Road H-1117 Budapest, Hungary
5.	Name of the Product	VOXEL.IOS
6.	Product Type	Intraoral scanner
7.	Short description of the Product	Optical 3D intraoral scanner for dental office use
8.	Type of Certification	Class I Medical Device
9.	Certification issued by	Original Manufacturer, based on their original medical CE certification documents
10.	Above mentioned Product conforms to the requirements of the following documents, per original Conformity documents	<ul style="list-style-type: none"> • EN ISO 13485:2016 • EN 1041:2008 • EN ISO 14971:2019 • EN 60601-1-2:2015 • EN ISO 10993-1:2018 • EN ISO 10993-10:2013 • MEDDEV 2.7/1 rev.4:2016 • EN ISO 15223-1:2016 • EN1640-2009 • EN 60601-1:2006+A1:2013 • ISO 7405:2008 • EN ISO 10993-5:2009 • EN ISO 17664:2017 • MEDDEV 2.12/1-rev.8
11.	Place of issue	Budapest
12.	Date of issue	01.08.2022
13.	Representative of the Issuer	Tamas Liskai
14.	Function of the Representative	CEO
<p>This conformity statement is for informational purposes only. Issuance of declaration of conformity is under the sole responsibility of the OEM.</p>		