



EU Declaration of Conformity

Manufacturer **Dental Wings Inc.**
160 Rue St-Viateur E
Montréal QC H2T 1A8
CANADA

SRN: CA-MF-000013837

declares under sole responsibility that the dental 3D scanners:

Intraoral Scanner
Type DW-IO
Model 001, Model 010, Model 100
Basic UDI-DI (EU): ++D840DWIODV

meet the relevant provisions of the applicable directives and regulation, whereas the following require CE marking:

Regulation (EU) 2017/745 on medical devices
Directive 2014/53/EU relating to radio equipment
Directive 2011/65/EU on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment

A Technical File has been compiled in accordance with the requirements set out in Annex II and III of 2017/745 and complies with the the General Safety and Performance Requirements set out in Annex I of 2017/745 and equivalent requirements set out in the other applicable directives. The classification in accordance with Annex VIII of 2017/745 is class I. The products are not placed on the market in sterile condition, have no measuring function and are not reusable surgical instruments. The Technical File is available with our authorized representative: Dental Wings GmbH, Düsseldorf Platz 1, 09111 Chemnitz, Germany, SRN: DE-AR-000006868. Importer of the products is: Dental Wings GmbH, Karl-Ziegler-Str. 18, 12489 Berlin, Germany, SRN: DE-IM-000006871.

The following information is part of the product:

Quick Start Guides
Instructions for Use

To verify the requirements of the directive and regulation, the following harmonized standards were applied:

IEC 60601-1:2012 / EN 60601-1:2010
IEC 60601-1-2:2014 / EN 60601-1-2:2010
IEC 60601-1-8:2013 / IEC / EN 62366:2014
IEC 62471:2006 / EN 62471:2008
IEC / EN 60825-1:2014
ISO 10993-1:2009 / EN ISO 10993-1:2017
ISO / EN ISO 17664:2017
IEC 62304:2015 / EN 62304:2008

The conformity assessment procedures were carried out in accordance with Annex II and III of 2017/745 and as defined in the other applicable directives.

Valid for: **DWIOC-10-001502 and higher**
DWIOF-02-0001 and higher
DWIOK-01-000001 and higher

Montréal, 2021-10-12
Location, date



Angelika Hähnel, Team Lead Quality & Regulatory
Dental Wings Inc.

Annex 1

Article No.	Model	Designation	GMDN code
6000-1	DW-IO-001	Intraoral Scanner cart Client Kit with Dental Wings / Institute Straumann AG marketing labels	38597 – Dental CAD/CAM system, chairside
6200-1	DW-IO-010	Intraoral Scanner (portable) Client with Dental Wings / Institute Straumann AG marketing labels	38597 – Dental CAD/CAM system, chairside
6300-1	DW-IO-100	Intraoral Scanner (laptop) Client with Dental Wings / Institute Straumann AG marketing labels	38597 – Dental CAD/CAM system, chairside