



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 (see Articles included)
Basic UDI-DI (EU): ++D840DWIODV

meet the relevant provisions of the applicable directives and regulation, whereas the following require issuing of an EU declaration of conformity:

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 Documentation 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 (rule 10). 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.

Authorized Representative: **Dental Wings GmbH**
Düsseldorfer Platz 1
09111 Chemnitz
Germany
SRN: DE-AR-000006868

Importer: **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, standards were applied as included in the Technical Documentation.

The conformity assessment procedures were carried out in accordance with Article 52 (7) of 2017/745 and as defined in the other applicable directives.

Valid for:

DWIOC-10-001502 and higher
DWIOP-02-0001 and higher
DWIOK-01-000001 and higher

Montréal, 2022-05-13

Location, date



Angelika Hähnel, Regulatory Affairs Manager
Dental Wings Inc.

Articles included:

Article No.	Model	Intended Use	Designation	GMDN code
6000-1	DW-IO-001	Dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.	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	
6300-1	DW-IO-100		Intraoral Scanner (laptop) Client with Dental Wings / Institute Straumann AG marketing labels	