

Declaration of Conformity

We, Dental Wings GmbH, as the *Physical Manufacturer*, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Medical Device Regulations in Thailand according to the Medical Device Act B.E. 2551 (2008) and the amended Medical Device Act B.E. 2562 (2019), 2nd edition.

Name and Address of Physical Manufacturer:

Dental Wings GmbH
Düsseldorfer Platz 1
09111 Chemnitz
Germany

Name and Address of Authorized Representative:

Straumann Group (Thailand) Company Limited
No. 1, 17th Floor
Q House Lumpini Building, South Sathorn Road
Tungmahamek Sub District, Sathorn District
Bangkok 10120

Medical Device(s):

coDiagnostiX, dental surgery treatment planning software

Risk Classification:

class II, rule 10(1)

Quality Management System Certificate:

Conformity Assessment Body issuing the certificate: QMS Certificate – ISO 13485:2016 & EN ISO 13485:2016

QMS Certificate number: MD 597650

Issuance date: 2019-02-28

Expiry date: 2021-11-30

Standards Applied:

ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes.
IEC 62304:2015/EN 62304:2008	Medical device software – Software life-cycle processes
ISO 15223-1:2016	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2012/EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
IEC / EN 62366:2016	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
MEDDEV 2.7.1: Rev 4, 2016	Guidelines on Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies

This declaration of conformity is valid from 2021-08-11

Authorized Signatory:

Chemnitz, 2021-08-11



Location, date

Dental Wings GmbH
Angelika Hähnel, Team Lead Quality & Regulatory