MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Dental Wings GmbH
Business address:	Düsseldorfer Platz 1 09111 Chemnitz Germany
Medical device(s):	coDiagnostiX
Classification:	Class IIa
GMDN code and term:	60883 - Dental treatment application Software
Scope of application:	Version 10.8 and higher

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

EU Quality Management System Certificate	**MDR 767912** (according Regulation (EU) 2017/745, Annex IX Chapter I and III)
Standards applied:	Conformity Assessment Procedure: Regulation (EU) 2017/745, Annex IX Chapter I and III
	IEC/EN 62304 – Medical Device Software – Software life-cycle processes
	IEC/EN 62366 – Medical devices – Application of usability engineering to medical devices
	ISO/EN 14971 – Medical Devices – Application of risk management to medical devices
	ISO/EN 15223-1 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	EU 2021/2226 - European Commission: Commission regulation (EU) No 2021/2226 on electronic instructions for use of medical devices

Authorised signatory:

Signature

Angelika Hähnel, Design Conformity & RA Manager — 2023-10-26

Name, Position — Date