Dental Wings GmbH, Düsseldorfer Platz 1, 09111 Chemnitz

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Declaration of Conformity

Name and Address of Manufacturer

Dental Wings GmbH
Düsseldorfer Platz 1
09111 Chemnitz
Germany

We, Dental Wings GmbH, hereby declare on our sole responsibility, that the product referred to herein meets the relevant provisions of the following EC Council Directives and Standards and conforms with the essential requirements (Annex I) of ASEAN-Medical Device Directive 2015.

(A) Particulars of medical device

Generic name: 3D software
Specified name: coDiagnostiX
Brand/model: CDX-001-MD
Country of origin: Made in Germany
Manufacturing site: Dental Wings GmbH, Düsseldorfer Platz 1, 09111 Chemnitz, Germany
Risk-based classification: Class IIa based on MDD 93/42/EEC, Annex II excluding section 4.
Class B based on AMDD 2015, Rule 10(i), Annex 2

(B) Medical Device Directives

Council Directive 93/42/EEC concerning medical devices

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
ID 2797

(C) Standard 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 15223-1:2021	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
IMEDDEV 2.7.1: Rev 4, 2016	Guidelines on Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies

(D) Manufacturer's quality system

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

QMS Certificate number: MD 597650

Issuance date: 2021-12-01

Expiry date: 2024-11-30

Signature:

Name: Angelika Haehnel

Position: Regulatory Affairs Manager