

Dental Wings GmbH, Düsseldorf Platz 1, 09111 Chemnitz

Kontakt

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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, Düsseldorf Platz 1, 09111 Chemnitz, Germany

Risk-based classification: Class IIa based on Regulation (EU) 2027/745 Annex VIII.

Class B based on AMDD 2015, Rule 10(i), Annex 2

(B) Medical Device Regulations

Regulation (EU) 2027/745 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
ISO 20417:2022	Information to be supplied by the manufacturer
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 Hähnel

Position: Design Conformity & RA Manager