Dental Wings GmbH | Düsseldorfer Platz 1 | 09111 Chemnitz | GERMANY

Contact
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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 that the below mentioned medical device -

i. Complies with all the requirements under the Act;
ii. Has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and
iii. Conform to the requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name: 3D software

Specified name: **See below list for details**

Brand/model: **See below list for details**

Manufacturer: Dental Wings GmbH, Düsseldorfer Platz 1, 09111 Chemnitz, Germany

Country of origin: Made in Germany

Manufacturing site: Dental Wings GmbH, Düsseldorfer Platz 1, 09111 Chemnitz, Germany

Risk-based classification: Class A

Classification rule: Rule 12 (Note: according to First Schedule on Rules of Classification of Medical Device)

GMDN code: 40935 (Diagnostic x-ray digital imaging system workstation)

Medical device registration number or any approval code:

(B) Quality Management System certificate (“QMS”)

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

(C) 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

(D) Product list:

Article No.	Product description
CDX-001-MD	coDiagnostiX

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorized Signatory:

Chemnitz, 2020-04-20

Location, date

Dental Wings GmbH
Angelika Hähnel, Quality & Regulatory Expert