



EC Declaration of Conformity

Manufacturer

**Dental Wings GmbH
Düsseldorfer Platz 1
09111 Chemnitz
Germany
SRN: DE-MF-000006867**

declares under sole responsibility that the medical software

coDiagnostiX
(including all articles listed in the annex on page 2)

Basic UDI-DI (EU): ++D835CODXDT

meets the relevant provisions of the applicable regulations, whereas the following regulation requires issuing of an EC declaration of conformity:

Regulation (EU) 2017/745 on medical devices

A Technical File has been compiled in accordance with the requirements set out in Annex II and III of Regulation (EU) 2017/745 and the product complies with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745. The classification in accordance with Annex VIII of Regulation (EU) 2017/745 is class IIa (rule 11).

To verify the requirements of the regulation, harmonized standards were applied.

The conformity assessment procedure was carried out in accordance with Article 52 (6) and Annex IX Chapter I and III of Regulation (EU) 2017/745 under assistance of the following Notified Body:

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

And a CE certificate with certification numbering MDR 767912 has been issued by this Notified Body.

Chemnitz, 2024-04-17

2028-09-03

Location, date

K. Günzel

Expiry date

Dental Wings GmbH

Katharina Günzel, Quality & Regulatory Specialist

Enthaltene Artikel / Articles included:

Article Code	Name	Description	Intended Use	Medical or non-medical device
CDX-001-MD	coDiagnostiX	coDiagnostiX product package (installation medium and eToken dongle)	dental surgery planning software	Medical device