UK Declaration of Conformity

Manufacturer

Dental Wings GmbH
Düsseldorfer Platz 1
09111 Chemnitz
Germany

declares under sole responsibility that the medical software

coDiagnostiX
(incl. all product variants, see Annex I)

meets the relevant provisions of the applicable directives, whereas the following directive requires UKCA marking:

UK Medical Device Regulations 2002 (as modified by Part II of Schedule 2A of the UK Medical Device Regulations 2002)

A Technical File has been compiled in accordance with the requirements set out in Annex II, 3., and complies with the Essential Requirements set out in Annex I of this directive. The classification in accordance with Annex IX of this directive is class IIa.
The Technical File is available with our UK representative.

UK representative:
Straumann Ltd.
10 Finsbury Square
London
EC2A 1AF
United Kingdom

Importer:
Straumann Ltd.
10 Finsbury Square
London
EC2A 1AF
United Kingdom

The following information is part of the product:

Instructions for Use

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

The conformity assessment procedures were carried out in accordance with Annex II under assistance of the following Approved Body:

BSI UK
Kitemark Court Davy Avenue Knowhill
Milton Keynes MK5 8PP
United Kingdom
ID 0086

Chemnitz, 2023-10-26
Ort, Datum
Location, date

2028-09-02
Ablaufdatum
Expiry date

Dental Wings GmbH
Angelika Hähnel, Design Conformity & RA Manager

Annex 1

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