

Declaration of Conformity

DEMONSTRATION OF CONFORMITY WITH RECOGNIZED STANDARDS TO SATISFY THE SAFETY AND EFFECTIVENESS REQUIREMENTS OF THE CANADIAN MEDICAL DEVICES REGULATIONS

Name of the medical device as it appears on the label: coDiagnostiX

Name of the Manufacturer of the medical device: Dental Wings GmbH

1. List of recognized standard(s) applicable in part or in whole to this Medical Device:

Full name of Standard(s) as stated on the <i>TPD Recognized Standards List</i>
IEC 62366:2006/A1:2014 Medical devices - Application of usability engineering to medical devices
IEC 62304:2015 Medical device software - Software life cycle processes
ISO 14971:2012 Previous standard is recognized: ISO 14971: 2007 Medical devices - Application of risk management to medical devices

In the case where only specific parts or Sections of a recognized standard apply to the device, *Sections 2 through 7 must be completed.*

In the case where all parts and Sections of a recognized standard apply to the device, *Section 5 through 7 must be completed.*

2. In the case where only specific parts or Sections of a recognized standard apply to the device, note the requirements that are not applicable to the medical device:

Recognized Standard(s)	Inapplicable Requirements of the Recognized Standard

Canada

3. In the case where only specific parts or Sections of a recognized standard apply to the device, note the deviations from the recognized standard(s). For example: To meet requirements of other Federal or Provincial legislation in Canada.

Name of Recognized Standard	Deviation

4. In the case where a standard has been adapted, note the requirements of the standard(s) have been adapted for application to this medical device. For example: In the case of a standard that offers alternative methods, specify which method has been followed.

Standard	Adapted Section(s)

5. The medical device which was tested against the recognized standard(s) is identical to the medical device intended to be marketed in Canada:

Yes

No

If the answer above is No, the difference(s) between the tested medical device and the medical device intended to be marketed in Canada are as follows:

Given the difference(s) between the tested medical device and the medical device intended to be marketed in Canada, the application of the recognized standard(s) is justified for the following reason(s):

6. An independent testing laboratory or certification body was used to determine the conformance of the medical device with the recognized standard(s):

Yes

No

If the answer to the above is Yes, the name and address of the testing laboratory or certification body and their accreditations are as follows:

Name and Address of Testing Laboratory or Certification Body	International, National or Provincial Accreditations of the Testing Laboratory or Certification Body
BSI Group The Netherlands B.V. (NB 2797) Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands CE certificate No. CE596668	ANSI-ASQ National Accreditation Board (ANAB)
Managed by: BSI Group America Inc. 12950 Worldgate Drive, Suite 800 Herndon, VA 20170-6007 USA ISO 13485 certificate No. MDSAP 693388	ANSI-ASQ National Accreditation Board (ANAB) and UKAS (United Kingdom Accreditation Service)

7. As a senior official of the manufacturer, having responsibility for the regulatory compliance of the medical device with the requirements of the Canadian *Medical Devices Regulations* and this Declaration of Conformity, I hereby declare that the information I have provided in support of the safety and effectiveness of the medical device to be true and accurate.

I also acknowledge that any false statement made with respect to the conformity of the medical device with an applicable recognized standard(s), or a determination by Health Canada that the medical device does not conform to the requirements of the recognized standard(s), could result in the suspension of any medical device licence which has been issued for the medical device subject of this Declaration of Conformity.

Name of Senior Official Frank Stockmann, _____
Title of Senior Official Managing Director Dental Wings GmbH____
Signature of Senior Official F. Stockmann
Date: 2019-12-03