

EU Declaration of Conformity



Document No.: SDS_EU_DoC_003_05

Manufacturer and Address:	Sirona Dental Systems GmbH Fabrikstraße 31, 64625 Bensheim, Germany
SRN:	DE-MF-000000029
Medical Device Name:	Endo Tabletop (Type: D3887)
Basic UDI-DI:	++E276EndoTTV01SV
Classification according to Annex VIII (2017/745/EU):	Ila acc. to Rule 9
Common Specifications:	Not applicable

Intended Use:

The device is used in dentistry to drive endodontic instruments for the mechanical preparation of the patient's root canal and cavity. Some models incorporate an electronic apex locator that assists the operator to locate the file tip inside the root canal.

We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Regulation 2017/745/EU and 2011/65/EU.

Any modification to the product, not authorized by us, will invalidate this declaration.

Valid from manufacturing date: 2023-04-18

The conformity of the full quality assurance system (Regulation 2017/745/EU, Annex IX) is certified by:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany

Certificate ID: G10 031247 0089 Rev. 01

The identification number of the notified body for implementation of the procedure is 0123.

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The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: ,
Directive 2014/53/EU (OJEU L 153/62, 22.05.2014)

The notified body VDE Prüf- und Zertifizierungsinstitut GmbH, 0366 performed an examination according article 3, 1. (b) and 3, 2. and issued the EU-type examination certificate No. 40056677.

Harmonized Standards applied:
EN 301 489-17 V 3.2.4; EN 300 328 V 2.2.2

Product Models /

Model: X-Smart Pro+ (REF: 6779016)

Types and Identification (Ref.-Number):

Model: X-Smart Pro (REF: 6779008)

Product variants / configurations:

Not applicable

Bensheim: April 18th, 2023

Mr. N. Plate
Group Vice President

Mr. J. Braasch
Manager Regulatory Compliance

The declaration certifies the compliance according to Annex I of Regulation 2017/745/EU.
Conditions of guarantee and liability are dealt within our General Conditions of Sale.