REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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

Manufacturer and Address:	**SIRONA Dental Systems GmbH** **Fabrikstraße 31** **64625 Bensheim** **Germany**
SRN:	**DE-MF-000000029**
Medical Device Name:	**Endo Tabletop** (Type: D3778)
Basic UDI-DI: *UDI-DI / int. Reference:*	**++E276EndoTTV01SV**
Classification according to Annex VIII (2017/745/EU):	**IIa acc. to Rule 9**
Common Specifications:	**None**

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.

Valid from manufacturing date: ***2025-07-14***

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

TÜV SÜD Product Service GmbH

Ridlerstraße 65
80339 München
Germany

Certificate ID:
G15 031247 0098

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

Bensheim: July 14th, 2025

Mr. N. Plate	Mr. J. Braasch
Managing Director	*Regulatory Affairs Manager*

The declaration certifies the compliance according to Annex I of Regulation 2017/745/EU.

Product Models / Types and Identification (Ref.-Number):	**6779016**	**X-Smart Pro+**
	6779008	**X-Smart Pro**
Product variants / configurations:	**Not applicable**	

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