

MANUFACTURER'S DECLARATION OF CONFORMITY					
RECORD ID	SDS_EU_DoC_MDR_111	RECORD REVISION	41	PAGE NO	Page 1 of 5

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:	Straight and contra angle handpieces
Basic UDI-DI:	++E276ContraangleV01HJ
UDI-DI / int. Reference:	
Classification according to Annex VIII (2017/745/EU):	Ila, Rule 9
Common Specifications:	None

Intended Use:

The intended use of straight and contra-angle handpieces is to transmit the torque from a dental motor to a dental instrument (like a bur), handled by trained dental personnel in dental practices and laboratories.

Valid from manufacturing date: 2026-07-21

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

Control Information of Manufacturers Declaration of Conformity EUMDR Class Iix					
DOCUMENT ID	5000-TP-04-001-0001m	REVISION LEVEL	4	QMS	SDS GmbH

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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: 2026-07-21

Place and date



Niels Plate

GVP Head of CTS R&D



Wolfram Müller

Regulatory Affairs Manager

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

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MANUFACTURER'S DECLARATION OF CONFORMITY				 Dentsply Sirona	
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Product Models / Types and Identification

<i>Name</i>	<i>REF</i>
<i>T1 Energo 1:5 L</i>	<i>6812056</i>
<i>T1 Energo 1:1 L</i>	<i>6812064</i>
<i>T1 Energo 5:1 L</i>	<i>6812072</i>
<i>T2 Energo 1:5 L</i>	<i>6812080</i>
<i>T2 Energo 1:1 L</i>	<i>6812098</i>
<i>T2 Energo 5:1 L</i>	<i>6812106</i>
<i>T3 Energo 1:5</i>	<i>6812114</i>
<i>T3 Energo 1:1</i>	<i>6812122</i>
<i>T3 Energo 5:1</i>	<i>6812130</i>
<i>T1 Energo S 1:5 L</i>	<i>6812148</i>
<i>T1 Energo S 1:1 L</i>	<i>6812155</i>
<i>T1 Energo S 5:1 L</i>	<i>6812163</i>
<i>Energo SH 1:1 L</i>	<i>6853340</i>
<i>Energo SH 1:1</i>	<i>6853357</i>
<i>Energo Prophy</i>	<i>6853365</i>
<i>Energo EVA 04 L</i>	<i>6853373</i>
<i>Energo EVA 11</i>	<i>6853381</i>
<i>Energo Endo 6:1 L</i>	<i>6853399</i>
<i>Energo Endo 6:1</i>	<i>6853407</i>
<i>T4 Energo 1:1</i>	<i>6853415</i>
<i>T4 Energo SH 1:1</i>	<i>6853423</i>

<i>Name</i>	<i>REF (internal)</i>	<i>REF (Midwest)</i>
<i>Midwest® T1 Energo S 1:5 L</i>	<i>6814680</i>	<i>875305</i>
<i>Midwest® T1 Energo S 1:1 L</i>	<i>6814698</i>	<i>875310</i>

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<i>Midwest® T1 Energo 1:5 L</i>	6819796	875315
<i>Midwest® T1 Energo 1:1 L</i>	6819804	875320
<i>Midwest® T1 Energo 5:1 L</i>	6819812	875325
<i>Midwest® T2 Energo M 1:5 L</i>	6814656	875401
<i>Midwest® T2 Energo 1:5 L</i>	6814664	875415
<i>Midwest® T2 Energo 1:1 L</i>	6814672	875420
<i>Midwest® T2 Energo 5:1 L</i>	6819820	875425
<i>Midwest® Energo SH 1:1 L</i>	6853431	875330
<i>Midwest® Energo Prophy</i>	6853449	875680
<i>Midwest® Energo EVA 11</i>	6853456	875681
<i>Midwest® Energo Endo 6:1 L</i>	6853464	875625
<i>Midwest® Energo Endo 6:1</i>	6853472	875725

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<i>Name</i>	<i>REF</i>
<i>Midwest® T1 Energo 1:5 L</i>	<i>6853613</i>
<i>Midwest® T1 Energo S 1:5 L</i>	<i>6853621</i>
<i>Midwest® T2 Energo 1:5 L</i>	<i>6853639</i>
<i>Midwest® T1 Energo 1:1 L</i>	<i>6853647</i>
<i>Midwest® T1 Energo S 1:1 L</i>	<i>6853654</i>
<i>Midwest® T2 Energo 1:1 L</i>	<i>6853662</i>
<i>Midwest® Energo Prophy</i>	<i>6853670</i>
<i>Midwest® Energo Endo 6:1 L</i>	<i>6853688</i>

End of document.

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