

EU Declaration of Conformity



Document No.: SDS_EU_DoC_MDR_111_37

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
Classification according to Annex VIII (2017/745/EU):	Class IIa, Rule 9
Common Specifications:	None

Intended Purpose

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.

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.

Valid from manufacturing date: 2023-12-05

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

TUV SUD 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.

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.

Bensheim: 2024-02-16

Place and date



Niels Plate
Group Vice President



Wolfram Müller
Regulatory Compliance Manager

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Product Models / Types and Identification (Ref.-Number):

Name	REF		
T1 Energo 1:5 L	6812056		
T1 Energo 1:1 L	6812064		
T1 Energo 5:1 L	6812072		
T2 Energo 1:5 L	6812080		
T2 Energo 1:1 L	6812098		
T2 Energo 5:1 L	6812106		
T3 Energo 1:5	6812114		
T3 Energo 1:1	6812122		
T3 Energo 5:1	6812130		
T1 Energo S 1:5 L	6812148		
T1 Energo S 1:1 L	6812155		
T1 Energo S 5:1 L	6812163		
		REF	Midwest-Nr
Midwest® T1 Energo S 1:5 L	6814680	875305	
Midwest® T1 Energo S 1:1 L	6814698	875310	
Midwest® T1 Energo 1:5 L	6819796	875315	
Midwest® T1 Energo 1:1 L	6819804	875320	
Midwest® T1 Energo 5:1 L	6819812	875325	
Midwest® T2 Energo M 1:5 L	6814656	875401	
Midwest® T2 Energo 1:5 L	6814664	875415	
Midwest® T2 Energo 1:1 L	6814672	875420	
Midwest® T2 Energo 5:1 L	6819820	875425	