

DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

This declaration of conformity is issued under the sole responsibility of rotatec GmbH in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical devices, listed in the following Article list meet the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

Manufacturers Name:	rotatec GmbH
Manufacturers Address:	Rütistrasse 6, Appenzell, Switzerland
	SRN (Single Registration Number): CH-MF-000031960
Basic UDI-DI:	76304771DentalPolishersK5
Name of the Device (s):	Polisher, Dental
Product code:	Q010101 Dental Restoration Devices
	UMDNS 16-412
Intendent use:	The Polisher, Dental are intended for laboratory and dental applications in clinics and hospital, both chair side and within the dental oral orifice.
Classification with rule number:	Class IIa according to Rule 5 of Annex VIII of the REGULATION (EU) 2017/745
Conformity assessment route:	REGULATION (EU) 2017/745 Annex IX, Conformity assessment based on a quality management system, according to chapter I and on assessment of technical documentation, according to chapter II
Notified Body Name and address:	medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart / Germany; The registration-number of the European Notified Body is 0483
Valid until:	2029-07-23

Identification of certificates issued:

Name of certificate	Certificate number	Valid until:
EU Quality Management System Certificate	D1510700003	2029-07-23

SIGNATURE:

NAME: STEFAN Daniel

FUNCTION: CEO / PRRC

Place and date of issue: Appenzell, 2024-08-13

REF / Article No.	Name of medical device	MDR Class	UDI-DI	Basic UDI-DI	Legal Manufacturer	UMDNS
CM2.314.030x012	Polisher, Dental	Ila	7630477137935	76304771DentalPolishersK5	rotatec GmbH	16-412
CM3.204.100x010	Polisher, Dental	Ila	7630477135191	76304771DentalPolishersK5	rotatec GmbH	16-412
CM3.204.100x012	Polisher, Dental	Ila	7630477137942	76304771DentalPolishersK5	rotatec GmbH	16-412
CM5.204.060x010	Polisher, Dental	Ila	7630477135207	76304771DentalPolishersK5	rotatec GmbH	16-412
CM5.204.060x012	Polisher, Dental	Ila	7630477137959	76304771DentalPolishersK5	rotatec GmbH	16-412
D1.204.050x025	Polisher, Dental	Ila	7630477137966	76304771DentalPolishersK5	rotatec GmbH	16-412
D1.204.050x100	Polisher, Dental	Ila	7630477135214	76304771DentalPolishersK5	rotatec GmbH	16-412
D2.204.030x025	Polisher, Dental	Ila	7630477137973	76304771DentalPolishersK5	rotatec GmbH	16-412
D2.204.030x100	Polisher, Dental	Ila	7630477135221	76304771DentalPolishersK5	rotatec GmbH	16-412
D4.204.090x025	Polisher, Dental	Ila	7630477137980	76304771DentalPolishersK5	rotatec GmbH	16-412
D4.204.090x100	Polisher, Dental	Ila	7630477135238	76304771DentalPolishersK5	rotatec GmbH	16-412
D5.204.065x025	Polisher, Dental	Ila	7630477137997	76304771DentalPolishersK5	rotatec GmbH	16-412
D5.204.065x100	Polisher, Dental	Ila	7630477135245	76304771DentalPolishersK5	rotatec GmbH	16-412
DM1.204.050x025	Polisher, Dental	Ila	7630477138000	76304771DentalPolishersK5	rotatec GmbH	16-412
DM1.204.050x100	Polisher, Dental	Ila	7630477135986	76304771DentalPolishersK5	rotatec GmbH	16-412
DM2.204.030x025	Polisher, Dental	Ila	7630477138017	76304771DentalPolishersK5	rotatec GmbH	16-412
DM2.204.030x100	Polisher, Dental	Ila	7630477135962	76304771DentalPolishersK5	rotatec GmbH	16-412
DM4.204.090x025	Polisher, Dental	Ila	7630477138024	76304771DentalPolishersK5	rotatec GmbH	16-412
DM4.204.090x100	Polisher, Dental	Ila	7630477135962	76304771DentalPolishersK5	rotatec GmbH	16-412
DM5.204.065x025	Polisher, Dental	Ila	7630477138031	76304771DentalPolishersK5	rotatec GmbH	16-412
DM5.204.065x100	Polisher, Dental	Ila	7630477135955	76304771DentalPolishersK5	rotatec GmbH	16-412
E1.204.050x025	Polisher, Dental	Ila	7630477138048	76304771DentalPolishersK5	rotatec GmbH	16-412
E1.204.050x100	Polisher, Dental	Ila	7630477135252	76304771DentalPolishersK5	rotatec GmbH	16-412
E2.204.030x025	Polisher, Dental	Ila	7630477138055	76304771DentalPolishersK5	rotatec GmbH	16-412
E2.204.030x100	Polisher, Dental	Ila	7630477135269	76304771DentalPolishersK5	rotatec GmbH	16-412
E3.204.100x025	Polisher, Dental	Ila	7630477138062	76304771DentalPolishersK5	rotatec GmbH	16-412
E3.204.100x100	Polisher, Dental	Ila	7630477135276	76304771DentalPolishersK5	rotatec GmbH	16-412
E4.204.090x025	Polisher, Dental	Ila	7630477138079	76304771DentalPolishersK5	rotatec GmbH	16-412
E4.204.090x100	Polisher, Dental	Ila	7630477135283	76304771DentalPolishersK5	rotatec GmbH	16-412
E5.204.065x025	Polisher, Dental	Ila	7630477138086	76304771DentalPolishersK5	rotatec GmbH	16-412
E5.204.065x100	Polisher, Dental	Ila	7630477135290	76304771DentalPolishersK5	rotatec GmbH	16-412
F1.204.050x010	Polisher, Dental	Ila	7630477135306	76304771DentalPolishersK5	rotatec GmbH	16-412
F1.204.050x012	Polisher, Dental	Ila	7630477138093	76304771DentalPolishersK5	rotatec GmbH	16-412
F2.204.030x010	Polisher, Dental	Ila	7630477135313	76304771DentalPolishersK5	rotatec GmbH	16-412
F2.204.030x012	Polisher, Dental	Ila	7630477138109	76304771DentalPolishersK5	rotatec GmbH	16-412
F4.204.090x010	Polisher, Dental	Ila	7630477135320	76304771DentalPolishersK5	rotatec GmbH	16-412
F4.204.090x012	Polisher, Dental	Ila	7630477138116	76304771DentalPolishersK5	rotatec GmbH	16-412
F5.204.065x010	Polisher, Dental	Ila	7630477135337	76304771DentalPolishersK5	rotatec GmbH	16-412
F5.204.065x012	Polisher, Dental	Ila	7630477138123	76304771DentalPolishersK5	rotatec GmbH	16-412
T1.204.045x010	Polisher, Dental	Ila	7630477135405	76304771DentalPolishersK5	rotatec GmbH	16-412
T1.204.045x012	Polisher, Dental	Ila	7630477141833	76304771DentalPolishersK5	rotatec GmbH	16-412
T2.204.030x010	Polisher, Dental	Ila	7630477135412	76304771DentalPolishersK5	rotatec GmbH	16-412
T2.204.030x012	Polisher, Dental	Ila	7630477141840	76304771DentalPolishersK5	rotatec GmbH	16-412
T4.204.090x010	Polisher, Dental	Ila	7630477135429	76304771DentalPolishersK5	rotatec GmbH	16-412
T4.204.090x012	Polisher, Dental	Ila	7630477141857	76304771DentalPolishersK5	rotatec GmbH	16-412
T5.204.065x010	Polisher, Dental	Ila	7630477135436	76304771DentalPolishersK5	rotatec GmbH	16-412
T5.204.065x012	Polisher, Dental	Ila	7630477141864	76304771DentalPolishersK5	rotatec GmbH	16-412
TD10.204.140x006	Polisher, Dental	Ila	7630477141871	76304771DentalPolishersK5	rotatec GmbH	16-412
TD10.204.140x010	Polisher, Dental	Ila	7630477135443	76304771DentalPolishersK5	rotatec GmbH	16-412
TD8.204.110x006	Polisher, Dental	Ila	7630477141888	76304771DentalPolishersK5	rotatec GmbH	16-412
TD8.204.110x010	Polisher, Dental	Ila	7630477135450	76304771DentalPolishersK5	rotatec GmbH	16-412
V1.204.050x010	Polisher, Dental	Ila	7630477135467	76304771DentalPolishersK5	rotatec GmbH	16-412
V1.204.050x012	Polisher, Dental	Ila	7630477141895	76304771DentalPolishersK5	rotatec GmbH	16-412
V10.204.140x006	Polisher, Dental	Ila	7630477141901	76304771DentalPolishersK5	rotatec GmbH	16-412
V10.204.140x010	Polisher, Dental	Ila	7630477135474	76304771DentalPolishersK5	rotatec GmbH	16-412
V2.204.030x010	Polisher, Dental	Ila	7630477135481	76304771DentalPolishersK5	rotatec GmbH	16-412
V2.204.030x012	Polisher, Dental	Ila	7630477141918	76304771DentalPolishersK5	rotatec GmbH	16-412
V4.204.090x010	Polisher, Dental	Ila	7630477135498	76304771DentalPolishersK5	rotatec GmbH	16-412
V4.204.090x012	Polisher, Dental	Ila	7630477141925	76304771DentalPolishersK5	rotatec GmbH	16-412
V5.204.065x010	Polisher, Dental	Ila	7630477135504	76304771DentalPolishersK5	rotatec GmbH	16-412
V5.204.065x012	Polisher, Dental	Ila	7630477141932	76304771DentalPolishersK5	rotatec GmbH	16-412
V8.204.110x006	Polisher, Dental	Ila	7630477141949	76304771DentalPolishersK5	rotatec GmbH	16-412
V8.204.110x010	Polisher, Dental	Ila	7630477135511	76304771DentalPolishersK5	rotatec GmbH	16-412
W1.204.050x010	Polisher, Dental	Ila	7630477135528	76304771DentalPolishersK5	rotatec GmbH	16-412
W1.204.050x012	Polisher, Dental	Ila	7630477141956	76304771DentalPolishersK5	rotatec GmbH	16-412
W2.204.030x010	Polisher, Dental	Ila	7630477135535	76304771DentalPolishersK5	rotatec GmbH	16-412
W2.204.030x012	Polisher, Dental	Ila	7630477141963	76304771DentalPolishersK5	rotatec GmbH	16-412
W4.204.090x010	Polisher, Dental	Ila	7630477135542	76304771DentalPolishersK5	rotatec GmbH	16-412

REF / Article No.	Name of medical device	MDR Class	UDI-DI	Basic UDI-DI	Legal Manufacturer	UMDNS
W4.204.090x012	Polisher, Dental	Ila	7630477141970	76304771DentalPolishersK5	rotatec GmbH	16-412
Z1.204.050x010	Polisher, Dental	Ila	7630477135559	76304771DentalPolishersK5	rotatec GmbH	16-412
Z1.204.050x012	Polisher, Dental	Ila	7630477141987	76304771DentalPolishersK5	rotatec GmbH	16-412
Z10.204.140x006	Polisher, Dental	Ila	7630477141994	76304771DentalPolishersK5	rotatec GmbH	16-412
Z10.204.140x010	Polisher, Dental	Ila	7630477135566	76304771DentalPolishersK5	rotatec GmbH	16-412
Z2.204.030x010	Polisher, Dental	Ila	7630477135573	76304771DentalPolishersK5	rotatec GmbH	16-412
Z2.204.030x012	Polisher, Dental	Ila	7630477142007	76304771DentalPolishersK5	rotatec GmbH	16-412
Z4.204.090x010	Polisher, Dental	Ila	7630477135580	76304771DentalPolishersK5	rotatec GmbH	16-412
Z4.204.090x012	Polisher, Dental	Ila	7630477142014	76304771DentalPolishersK5	rotatec GmbH	16-412
Z5.204.065x010	Polisher, Dental	Ila	7630477135597	76304771DentalPolishersK5	rotatec GmbH	16-412
Z5.204.065x012	Polisher, Dental	Ila	7630477142021	76304771DentalPolishersK5	rotatec GmbH	16-412
Z8.204.110x006	Polisher, Dental	Ila	7630477142038	76304771DentalPolishersK5	rotatec GmbH	16-412
Z8.204.110x010	Polisher, Dental	Ila	7630477137409	76304771DentalPolishersK5	rotatec GmbH	16-412