

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:	76304771DentalCarbidesGS
Name of the Device (s):	Burs, Dental, Carbide
Product code:	Q010101 Dental Restoration Devices
	UMDNS 16-668
Intendent use:	The Burs, Dental, Carbides 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 6 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
SH1L.204.018x006	Burs, Dental, Carbide	Ila	7630477141710	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.204.021x006	Burs, Dental, Carbide	Ila	7630477141727	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.204.023x006	Burs, Dental, Carbide	Ila	7630477141734	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.204.027x006	Burs, Dental, Carbide	Ila	7630477141741	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.204.029x006	Burs, Dental, Carbide	Ila	7630477141758	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.006x006	Burs, Dental, Carbide	Ila	7630477141765	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.008x006	Burs, Dental, Carbide	Ila	7630477141772	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.010x006	Burs, Dental, Carbide	Ila	7630477141789	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.014x006	Burs, Dental, Carbide	Ila	7630477141796	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.018x006	Burs, Dental, Carbide	Ila	7630477141802	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.023x006	Burs, Dental, Carbide	Ila	7630477141819	76304771DentalCarbidesGS	rotatec GmbH	16-668
SH1L.205.027x006	Burs, Dental, Carbide	Ila	7630477141826	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1.204.008x005	Burs, Dental, Carbide	Ila	7630477133623	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1.314.008x005	Burs, Dental, Carbide	Ila	7630477133630	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1/2.204.006x005	Burs, Dental, Carbide	Ila	7630477133647	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1/2.314.006x005	Burs, Dental, Carbide	Ila	7630477133654	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1/2SL.314.006x005	Burs, Dental, Carbide	Ila	7630477133661	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1/4.314.005x005	Burs, Dental, Carbide	Ila	7630477133678	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1156.314.008x005	Burs, Dental, Carbide	Ila	7630477133685	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1157.314.010x005	Burs, Dental, Carbide	Ila	7630477133692	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1157SS.314.008x005	Burs, Dental, Carbide	Ila	7630477133708	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1158.314.012x005	Burs, Dental, Carbide	Ila	7630477133715	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1170L.314.010x005	Burs, Dental, Carbide	Ila	7630477133722	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1171.314.012x005	Burs, Dental, Carbide	Ila	7630477133739	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1556.314.008x005	Burs, Dental, Carbide	Ila	7630477133746	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1557.104.010x005	Burs, Dental, Carbide	Ila	7630477133753	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1557.314.010x005	Burs, Dental, Carbide	Ila	7630477133760	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1557SS.314.008x005	Burs, Dental, Carbide	Ila	7630477133777	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1558.314.012x005	Burs, Dental, Carbide	Ila	7630477133784	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC169.314.009x005	Burs, Dental, Carbide	Ila	7630477133791	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC169L.314.009x005	Burs, Dental, Carbide	Ila	7630477133807	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC170.314.010x005	Burs, Dental, Carbide	Ila	7630477133814	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1702.104.016x005	Burs, Dental, Carbide	Ila	7630477133821	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1703.104.010x005	Burs, Dental, Carbide	Ila	7630477133838	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1703L.104.010x005	Burs, Dental, Carbide	Ila	7630477133845	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC170L.314.010x005	Burs, Dental, Carbide	Ila	7630477133852	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC171L.314.012x005	Burs, Dental, Carbide	Ila	7630477133869	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1958.314.012x005	Burs, Dental, Carbide	Ila	7630477133876	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC1SL.314.008x005	Burs, Dental, Carbide	Ila	7630477133883	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2.104.010x005	Burs, Dental, Carbide	Ila	7630477133890	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2.204.010x005	Burs, Dental, Carbide	Ila	7630477133906	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2.314.010x005	Burs, Dental, Carbide	Ila	7630477133913	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC245.314.009x005	Burs, Dental, Carbide	Ila	7630477133920	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC245SS.314.009x005	Burs, Dental, Carbide	Ila	7630477133937	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC274H.314.016x005	Burs, Dental, Carbide	Ila	7630477133944	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2SL.205.010x005	Burs, Dental, Carbide	Ila	7630477133951	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2SL.314.010x005	Burs, Dental, Carbide	Ila	7630477133968	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC2SS.314.010x005	Burs, Dental, Carbide	Ila	7630477133975	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC3.104.012x005	Burs, Dental, Carbide	Ila	7630477133982	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC3.204.012x005	Burs, Dental, Carbide	Ila	7630477133999	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC3.314.012x005	Burs, Dental, Carbide	Ila	7630477134002	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC329.314.006x005	Burs, Dental, Carbide	Ila	7630477134019	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC330.314.008x005	Burs, Dental, Carbide	Ila	7630477134026	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC330L.314.008x005	Burs, Dental, Carbide	Ila	7630477134033	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC330S.313.008x005	Burs, Dental, Carbide	Ila	7630477134040	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC330SS.313.008x005	Burs, Dental, Carbide	Ila	7630477134057	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC331.314.010x005	Burs, Dental, Carbide	Ila	7630477134064	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC3312.314.006x005	Burs, Dental, Carbide	Ila	7630477134071	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC331L.314.010x005	Burs, Dental, Carbide	Ila	7630477134088	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC331SS.314.010x005	Burs, Dental, Carbide	Ila	7630477134095	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC332.314.012x005	Burs, Dental, Carbide	Ila	7630477134101	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC332L.314.012x005	Burs, Dental, Carbide	Ila	7630477134118	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC34.314.008x005	Burs, Dental, Carbide	Ila	7630477134125	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC35.204.010x005	Burs, Dental, Carbide	Ila	7630477134132	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC35.314.010x005	Burs, Dental, Carbide	Ila	7630477134149	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC35SS.313.010x005	Burs, Dental, Carbide	Ila	7630477134156	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC36.314.012x005	Burs, Dental, Carbide	Ila	7630477134163	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC37.314.014x005	Burs, Dental, Carbide	Ila	7630477134170	76304771DentalCarbidesGS	rotatec GmbH	16-668

REF / Article No.	Name of medical device	MDR Class	UDI-DI	Basic UDI-DI	Legal Manufacturer	UMDNS
TC37923.314.023x005	Burs, Dental, Carbide	Ila	7630477134187	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4.104.014x005	Burs, Dental, Carbide	Ila	7630477134194	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4.204.014x005	Burs, Dental, Carbide	Ila	7630477134200	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4.314.014x005	Burs, Dental, Carbide	Ila	7630477134217	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC48L10H.315.010x005	Burs, Dental, Carbide	Ila	7630477134224	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC48L12H.315.012x005	Burs, Dental, Carbide	Ila	7630477134231	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4SL.205.014x005	Burs, Dental, Carbide	Ila	7630477134248	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4SL.314.014x005	Burs, Dental, Carbide	Ila	7630477134255	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC4SS.314.014x005	Burs, Dental, Carbide	Ila	7630477134262	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC5.104.016x005	Burs, Dental, Carbide	Ila	7630477134279	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC5.204.016x005	Burs, Dental, Carbide	Ila	7630477134286	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC5.314.016x005	Burs, Dental, Carbide	Ila	7630477134293	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC556.204.008x005	Burs, Dental, Carbide	Ila	7630477134309	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC556.314.008x005	Burs, Dental, Carbide	Ila	7630477134316	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC556SS.314.008x005	Burs, Dental, Carbide	Ila	7630477134323	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC557.104.010x005	Burs, Dental, Carbide	Ila	7630477134330	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC557.314.010x005	Burs, Dental, Carbide	Ila	7630477134347	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC557L.314.010x005	Burs, Dental, Carbide	Ila	7630477134354	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC557SL.314.010x005	Burs, Dental, Carbide	Ila	7630477134361	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC557SS.314.010x005	Burs, Dental, Carbide	Ila	7630477134378	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC558.314.007x005	Burs, Dental, Carbide	Ila	7630477134385	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC558SL.314.007x005	Burs, Dental, Carbide	Ila	7630477134392	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC559.104.014x005	Burs, Dental, Carbide	Ila	7630477134408	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC56.314.008x005	Burs, Dental, Carbide	Ila	7630477134415	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC563L.104.023x005	Burs, Dental, Carbide	Ila	7630477134422	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC56SS.314.008x005	Burs, Dental, Carbide	Ila	7630477134439	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC57.314.010x005	Burs, Dental, Carbide	Ila	7630477134446	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC57L.314.010x005	Burs, Dental, Carbide	Ila	7630477134453	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC57SS.314.010x005	Burs, Dental, Carbide	Ila	7630477134460	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC58.314.012x005	Burs, Dental, Carbide	Ila	7630477134477	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC6.104.018x005	Burs, Dental, Carbide	Ila	7630477134484	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC6.204.018x005	Burs, Dental, Carbide	Ila	7630477134491	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC6.314.018x005	Burs, Dental, Carbide	Ila	7630477134507	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC699.314.009x005	Burs, Dental, Carbide	Ila	7630477134514	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC6SL.205.018x005	Burs, Dental, Carbide	Ila	7630477134521	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC6SL.316.018x005	Burs, Dental, Carbide	Ila	7630477134538	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7.104.021x005	Burs, Dental, Carbide	Ila	7630477134545	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7.204.021x005	Burs, Dental, Carbide	Ila	7630477134552	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7.314.021x005	Burs, Dental, Carbide	Ila	7630477134569	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC700.314.010x005	Burs, Dental, Carbide	Ila	7630477134576	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7006.314.018x005	Burs, Dental, Carbide	Ila	7630477134583	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC701.104.012x005	Burs, Dental, Carbide	Ila	7630477134590	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC701.314.012x005	Burs, Dental, Carbide	Ila	7630477134606	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC701L.314.012x005	Burs, Dental, Carbide	Ila	7630477134613	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC701SL.314.012x005	Burs, Dental, Carbide	Ila	7630477134620	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC702.104.016x005	Burs, Dental, Carbide	Ila	7630477134637	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC702.314.016x005	Burs, Dental, Carbide	Ila	7630477134644	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC702L.104.016x005	Burs, Dental, Carbide	Ila	7630477134651	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC702SL.314.016x005	Burs, Dental, Carbide	Ila	7630477134668	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC703.104.021x005	Burs, Dental, Carbide	Ila	7630477134675	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC703L.104.021x005	Burs, Dental, Carbide	Ila	7630477134682	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7104.314.014x005	Burs, Dental, Carbide	Ila	7630477134699	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7106.314.018x005	Burs, Dental, Carbide	Ila	7630477134705	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7404.314.014x005	Burs, Dental, Carbide	Ila	7630477134712	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7406.314.018x005	Burs, Dental, Carbide	Ila	7630477134729	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7408.314.023x005	Burs, Dental, Carbide	Ila	7630477134736	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7642.314.010x005	Burs, Dental, Carbide	Ila	7630477134743	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7664.315.015x005	Burs, Dental, Carbide	Ila	7630477134750	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7675.315.016x005	Burs, Dental, Carbide	Ila	7630477134767	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7714.315.016x005	Burs, Dental, Carbide	Ila	7630477134774	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7802.314.010x005	Burs, Dental, Carbide	Ila	7630477134781	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7803.314.012x005	Burs, Dental, Carbide	Ila	7630477134798	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7901.314.009x005	Burs, Dental, Carbide	Ila	7630477134804	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7902.314.010x005	Burs, Dental, Carbide	Ila	7630477134811	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC7903.314.012x005	Burs, Dental, Carbide	Ila	7630477134828	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC8.104.023x005	Burs, Dental, Carbide	Ila	7630477134835	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC8.204.023x005	Burs, Dental, Carbide	Ila	7630477134842	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC8.314.023x005	Burs, Dental, Carbide	Ila	7630477134859	76304771DentalCarbidesGS	rotatec GmbH	16-668

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TC84716.314.016x005	Burs, Dental, Carbide	Ila	7630477134866	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC856.314.016x005	Burs, Dental, Carbide	Ila	7630477134873	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC856.314.018x005	Burs, Dental, Carbide	Ila	7630477134880	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC85616.314.016x005	Burs, Dental, Carbide	Ila	7630477134897	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC85618.314.018x005	Burs, Dental, Carbide	Ila	7630477134903	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC8SL.205.023x005	Burs, Dental, Carbide	Ila	7630477134910	76304771DentalCarbidesGS	rotatec GmbH	16-668
TC8SL.314.023x005	Burs, Dental, Carbide	Ila	7630477134927	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCEF3.315.008x005	Burs, Dental, Carbide	Ila	7630477134934	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCEF4.314.010x005	Burs, Dental, Carbide	Ila	7630477134941	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCEF6.314.014x005	Burs, Dental, Carbide	Ila	7630477134958	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCEF9.314.014x005	Burs, Dental, Carbide	Ila	7630477134965	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC1.314.010x005	Burs, Dental, Carbide	Ila	7630477134972	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC1557.314.010x005	Burs, Dental, Carbide	Ila	7630477134989	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC2.314.012x005	Burs, Dental, Carbide	Ila	7630477134996	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC2/1.314.012x005	Burs, Dental, Carbide	Ila	7630477135009	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC330.314.008x005	Burs, Dental, Carbide	Ila	7630477135016	76304771DentalCarbidesGS	rotatec GmbH	16-668
TCKC557.314.010x005	Burs, Dental, Carbide	Ila	7630477135023	76304771DentalCarbidesGS	rotatec GmbH	16-668