EU Declaration of Conformity
Regarding Medical Device Regulation(EU)2017/745

Manufacturer

Company: Jining Orodeka Medical Equipment Co., LTD

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SRN: CN-MF-000034133

European Authorized Representative

Name: ORODEKA S.R.L.

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Product Name: Dental Root Canal File

Types: Engine Use K - file, Engine Use R - file, Engine Use H - file

EMDN Code: Q010507

Basic UDI-DI:

Engine Use H -file: 697284234EngineusehfileEH

Engine Use R -file: 697284234EngineuserfileHX

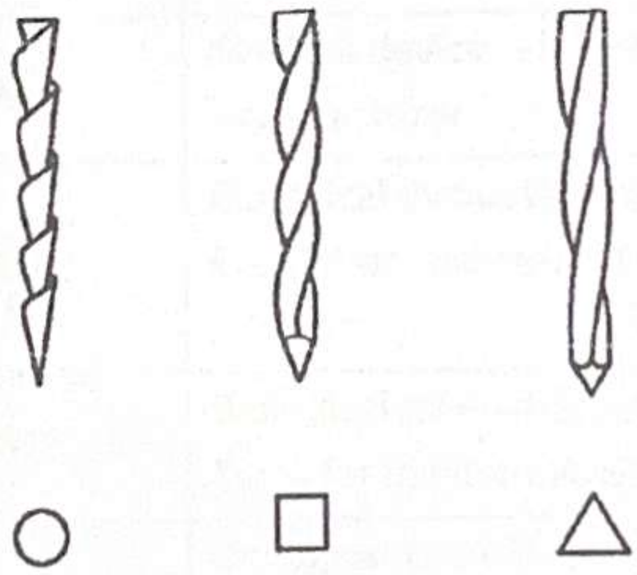
Engine Use K –file: 697284234EngineusekfileFJ

Classification: Class IIa

Rule: Rule 6, Paragraph 1, Annex VIII, Medical Device Regulation (EU)2017/745

Conformity assessment procedure: Annex IX Chapter I, Section 2 and 3

Intended Use: The Dental Root Canal File is intended to be connected to a handpiece for cleaning and shaping of root canal during root canal treatment.



CE 0197

The product adopts the module of "EC Declaration of Conformity" and the conformity assessment was performed according to Annex IX of Regulation (EU) 2017/745 has been assured via assessment of the quality management system by Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HZ 2161305-1
Issue date: 2025-05-29
Expiry date: 2030-05-28

We confirm our product meets the requirements of Medical Device Regulation（EU）2017/745 and the following standards and Common Specifications.

Applicable Standard

No.	Standard No.	Version	Title
1.	Medical Device Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
3.	EN ISO 14971	2019+A11:2021	Medical Device - Application of Risk Management in Medical Device
4.	CEN ISO/TR 24971	2020	Medical devices - Guidance on the application of ISO 14971
5.	EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied General requirements.
6.	EN ISO 20417	2021	Medical device -- Information to be supplied by the manufacturer
7.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
9.	EN ISO 10993-10	2023	Biological Evaluation of Medical Device –Part 10: Tests for skin sensitization
10.	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
11.	EN ISO 10993-18	2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
12.	EN ISO	2021	Biological evaluation of medical devices - Part 23:

	10993-23		Tests for irritation
13.	EN ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
14.	EN ISO 17665-1	2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
15.	ASTM F1980	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
16.	EN 62366-1	2015+AC: 2015 +AC:2016+A1: 2020	Medical devices-Application of usability engineering to medical devices
17.	EN 285	2015+A1:2021	Sterilization - Steam sterilizers - Large sterilizers
18.	EN 13060	2014+A1:2018	Small steam sterilizers
19.	EN ISO 9687	2015+A1:2018	Dentistry - Graphical symbols for dental equipment
20.	EN ISO 3630-1	2019	Dentistry - Root-canal instruments - Part 1: General requirements and test methods
21.	EN ISO 3630-5	2020	Dentistry - Endodontic instruments - Part 5: Shaping and cleaning instruments
22.	EN ISO 1797	2017	Dentistry - Shanks for rotary and oscillating instruments
23.	ASTM-D4169	2022	Standard Practice for Performance Testing of Shipping Containers and Systems
24.	EN 1639	2009	Dentistry- Medical devices for dentistry- Instruments
25.	EN ISO 10271	2020	Dentistry - Corrosion test methods for metallic materials
26.	EN ISO 7405	2018	Dentistry-Evaluation of biocompatibility of medical devices used in dentistry

Reference Guidance

Item.	Guidance	Title
1	MEDDEV 2.4/1 rev.9 (2010)	Medical devices: Guidance document: Classification of medical devices
2	MEDDEV 2.7.1 rev.4 (2016)	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
3	MEDDEV 2.12-1 rev.8	Guidelines On a Medical Devices Vigilance System

4	MEDDEV 2.12-2 rev.2	Guidelines On Post Market Clinical Follow-Up
5	MDCG 2020-5	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
6	MDCG 2020-6	Guidance on Sufficient Clinical Evidence for Legacy Devices
7	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
8	MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
9	MDCG 2021-24	Guidance on classification of medical devices
10	GHTF SG5/N2R8	Clinical Evaluation

Name and Signature: Position: PRRC

Date and Place: 2025.06.16, Jiomig