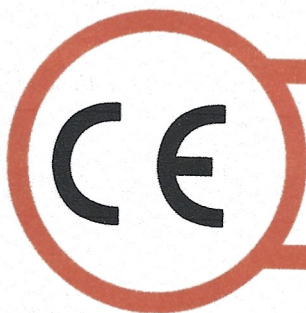




# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Fascinatio Boulevard 522, Unit 1.7,  
2909VA Capelle aan den IJssel, The  
Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971:2019  
EN ISO 15223-1:2021  
EN ISO 20417: 2021  
EN ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10: 2023  
EN ISO 10993-23: 2021

## Manufacturer

Name: JINING ORODEKA MEDICAL EQUIPMENT  
CO., LTD  
Address: West 15 Floor, XinchengFazhan East  
Building, Beihu District, Jining, 272000 Shandong,  
P.R. China  
SRN: CN-MF-000034133

## Product Information

Name: Root canal file  
Model: K - file, R - file, H - file, G-file  
EMDN: Q010507  
Basic UDI-DI: /  
Classification: Class I, according to Rule 5, Annex  
VIII, Regulation (EU) 2017/745

## Declaration

**Remark**

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Q010507-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2024.1.22

Position: GM Place: Jining/China

