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

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

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

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: Liu Mingfang Date: 2024.1.22

Position: GM Place: Jining/China