

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **Shenzhen Denco Medical Co., Ltd**
Address: Room 3108, Block 6, Tian'an Cloud Park , Bantian street, Longgang District, Shenzhen, 518129 , Guangdong P.R.China
Factory Address: Room 101,201,301B,401&801, Block 5, Renluo 6 Road No. 6, Shuikou Street, Huicheng District, Huizhou,516000 Guangdong P.R.China
(SRN: CN-MF-000014271)

We declare under our sole responsibility that /

the medical device: / Endo Extractors
specification: / E-MATE ES, E-MATE ES II, ET-60, ET-70, ET-80, ET-90, ET-100, ET-110, #30 , #40

classification and Rules: / Class I - Rule 5 subclause 1
according to Annex VIII of the Regulation (EU) 2017/745
EMDN code / description: / Q010199 - CONSERVATIVE DENTISTRY AND
ENDODONTICS DEVICES - OTHER
Basic -UDI-DI 69705149109FEAW

meets the regulatory requirement of the European Union Medical Device Regulation (EU)2017/745

Conformity assessment procedure: / Annex II+III of Regulation (EU) 2017/745
Applied standards: / EN ISO13485:2016+AC:2018+A11:2021, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021

Authorised Representative: / **Share Info GmbH**
Address: Am Schulzentrum 12, 41564 Kaarst, Germany
SRN: DE-AR-000005132

Signature: _____

Date:

2025-7-22

Position: GM

Place:

Shenzhen /China

