SHENZHEN ROGIN MEDICAL CO., LTD
Address: Room 3109, Block 6, Tian'an Cloud Park ,
Bantian street, Longgang District, Shenzhen, 518129,
Guangdong P.R.China

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **Shenzhen Rogin Medical Co., Ltd**
Address: Room 3109, Block 6, Tian'an Cloud Park , Bantian street, Longgang District, Shenzhen, 518129 , Guangdong P.R.China
（SRN：CN-MF-000012192）

We declare under our sole responsibility that /

the medical device: /	Dental Irrigation Needle
specification： /	**Endostar ENDOflex Needles**

classification and Rules: /	Class I –Rule 5 subclause 1 according to Annex VIII of the Regulation (EU) 2017/745
EMDN code / description: /	A010602 - DENTAL IRRIGATION NEEDLES
Basic -UDI-DI	6942007309ITGS

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: / **MedNet EC-REP GmbH**
Address: Borkstrasse 10,48163 Münster Germany
SRN: DE-AR-000000002

Signature:_____ Date: 2026.05.26

Position: GM Place: Shenzhen /China