

## EC Declaration of Conformity

Manufacturer: **Changzhou Sifary Medical Technology Co., Ltd.**  
**No. 99, Qingyang Road, Xuejia County, Xinbei District, Changzhou**  
**City, Jiangsu Province, China 213000**  
**Tel/Fax: 0519-85962691**

Authorized European Representative: **Llins Service & Consulting GmbH**  
**Obere Seegasse 34/2, 69124, Heidelberg, Germany**  
**Tel: +49 175 4870819**

Product name: **Obturation Pack Handpiece**  
Model Number: **Fast-Pack**  
**Endo Gutta Pack**

Classification (MDD, Annex IX): **I, rule 12**

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

#### General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended by Directive 2007/47/EC.

Standard Applied: All applied harmonized standards.

Notified Body: N/A

NB Identification number: N/A

(EC) Certificate(s): N/A

Expire date of the Certificate: N/A

Place, Date of Issue: **Changzhou, 2020-06-19**

Signature:



Name: **Tao Huan**

Position: **General Manager**