

Declaration of Conformity

Manufacturer: Changzhou Sifary Medical Technology Co., Ltd.
No. 99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, Jiangsu Province, China 213000

Authorized EU Representative: Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg, Germany

Product Name: Endodontic Obturation Devices
Product Model: Fast-Fill

Classification (MDD, Annex IX): Class IIa, rule 11

Conformity Assessment Route: Annex V

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the following Directive 93/42/EEC as amended by Directive 2007/47/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. All supporting documentations are retained under the premises of the manufacturer. Changzhou Sifary Medical Technology Co., Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:
Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EEC

Notified body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Deutschland, Germany


NB identification number: 0197

(EC) Certificate No.: DD 60148982 0001

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Changzhou, 2020.06.04
Place, date


_____, General Manager
Legally binding signature, Function