

EU Declaration of Conformity

Manufacturer: Chengdu Sani Medical Equipment Co., Ltd.
Add: Building 3 & Room 108, Building 1, No.408, Tengfei 4th Road, Southwest
Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan
Province, 610207, P.R. China
SRN : CN-MF-000011715

Whose Single Riomavix S.L.
Authorized EU- Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
Representative: E-mail: leis@riomavix.com
Tel.: +34 658 396 230
SRN: ES-AR-000001202

Product Name: Gutta Percha Points
Basic UDI-DI: 697060203GPP0018Z
Model: See annex
Intended Purpose: This product is a dental solid root canal filling material, used for root canal filling
and sealing in root canal treatment.

Product Code EMDN code: Q01010401,
GMDN code: 45412
MDN code: MDN 1103

Classification (MDR, Annex VIII): Class IIa, Rule 8.

Conformity Assessment Route: Chapter I and Chapter III of Annex IX (conformity assessment based on a quality management system and on assessment of technical documentation), and including an assessment of the technical documentation as specified in section 4 of the Annex, Regulation (EU) 2017/745 (MDR).

We herewith declare under our sole responsibility that the above-mentioned products meet the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer. We statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14971:2019, EN ISO 20417:2021, ISO 10993-1:2020, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2021, ISO 10993-11:2018, ISO 10993-23:2021, EN ISO 6877:2021, ISO 3630-1:2019, IEC 62366-1:2015/Amd 1:2020.

NOTIFIED BODY: SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
Notified body number: 1639

Certificate No.: CN25/00001182
Certificate Validity: 26 February 2025 – 26 February 2030

Signature:

Name: Chunxia He
Title: General manager
Place/Date: China, 26 February 2025



Annex:Model list

010/02	015/03	015/04	015/05	015/06	015/08	015/10
015/02	020/03	020/04	020/05	020/06	020/08	020/10
020/02	025/03	025/04	025/05	025/06	025/08	025/10
025/02	030/03	030/04	030/05	030/06	030/08	030/10
030/02	035/03	035/04	035/05	035/06	035/08	035/10
035/02	040/03	040/04	040/05	040/06	040/08	040/10
040/02	045/03	045/04	045/05	045/06	045/08	045/10
045/02	050/03	050/04	050/05	050/06	050/08	050/10
050/02	055/03	055/04	055/05	055/06	055/08	055/10
055/02	060/03	060/04	060/05	060/06	060/08	060/10
060/02	070/03	070/04	070/05	070/06	070/08	070/10
070/02	080/03	080/04	080/05	080/06	080/08	080/10
080/02	090/03	090/04	090/05	090/06	090/08	090/10
090/02	100/03	100/04	100/05	100/06	100/08	100/10
100/02	110/03	110/04	110/05	110/06	110/08	110/10
110/02	120/03	120/04	120/05	120/06	120/08	120/10
120/02	130/03	130/04	130/05	130/06	130/08	130/10
130/02	140/03	140/04	140/05	140/06	140/08	140/10
140/02	035/12	060/12	110/12	F2	F	D3
015/12	040/12	070/12	120/12	F3	FM	D4
020/12	045/12	080/12	130/12	F4	M	D5
025/12	050/12	090/12	140/12	F5	ML	X1
030/12	055/12	100/12	F1	XF	L	X2
Small	Primary	Medium	Large	FF	XL	X3
MF	X4	X5	250 13.5mm	280 13.5mm	250 14.5mm	280 14.5mm
010/02-H	015/03-H	015/04-H	015/05-H	015/06-H	015/08-H	015/10-H
015/02-H	020/03-H	020/04-H	020/05-H	020/06-H	020/08-H	020/10-H
020/02-H	025/03-H	025/04-H	025/05-H	025/06-H	025/08-H	025/10-H
025/02-H	030/03-H	030/04-H	030/05-H	030/06-H	030/08-H	030/10-H
030/02-H	035/03-H	035/04-H	035/05-H	035/06-H	035/08-H	035/10-H
035/02-H	040/03-H	040/04-H	040/05-H	040/06-H	040/08-H	040/10-H
040/02-H	045/03-H	045/04-H	045/05-H	045/06-H	045/08-H	045/10-H
045/02-H	050/03-H	050/04-H	050/05-H	050/06-H	050/08-H	050/10-H
050/02-H	055/03-H	055/04-H	055/05-H	055/06-H	055/08-H	055/10-H
055/02-H	060/03-H	060/04-H	060/05-H	060/06-H	060/08-H	060/10-H
060/02-H	070/03-H	070/04-H	070/05-H	070/06-H	070/08-H	070/10-H
070/02-H	080/03-H	080/04-H	080/05-H	080/06-H	080/08-H	080/10-H
080/02-H	090/03-H	090/04-H	090/05-H	090/06-H	090/08-H	090/10-H
090/02-H	100/03-H	100/04-H	100/05-H	100/06-H	100/08-H	100/10-H
100/02-H	110/03-H	110/04-H	110/05-H	110/06-H	110/08-H	110/10-H
110/02-H	120/03-H	120/04-H	120/05-H	120/06-H	120/08-H	120/10-H
120/02-H	130/03-H	130/04-H	130/05-H	130/06-H	130/08-H	130/10-H
130/02-H	140/03-H	140/04-H	140/05-H	140/06-H	140/08-H	140/10-H
140/02-H	035/12-H	060/12-H	110/12-H	F2-H	F-H	D3-H
015/12-H	040/12-H	070/12-H	120/12-H	F3-H	FM-H	D4-H
020/12-H	045/12-H	080/12-H	130/12-H	F4-H	M-H	D5-H
025/12-H	050/12-H	090/12-H	140/12-H	F5-H	ML-H	X1-H
030/12-H	055/12-H	100/12-H	F1-H	XF-H	L-H	X2-H
Small-H	Primary-H	Medium-H	Large-H	FF-H	XL-H	X3-H
MF-H	X4-H	X5-H				