

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: Riomavix S.L.

Address: Calle de Almansa 55,1D, Madrid
28039 Spain

E-mail: leis@riomavix.com

Tel.: +34658396 230

SRN: ES-AR-000001202

Conformity Assessment

Conformity Assessment Procedure

Annex II+ Annex III + Article 19 of
Regulation (EU) 2017/745

Applicable Standards

EN ISO 15223-1:2021

EN ISO 14971:2019

EN ISO 20417: 2021

EN ISO 10993-1:2020

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN ISO 13485:2016

EN ISO 7551:2023

Manufacturer

Name: CHENGDU SANI MEDICAL EQUIPMENT
CO.,LTD.

Address: 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

Product Information

Name : ABSORBENT PAPER POINT

Model: See Annex

EMDN : Q01010401

Basic UDI-DI : 697060203APP0016K

Intended Use: It is used for root canal cleaning,
suction and dressing change in root canal treatment.

Classification: Class Is, according to Rule 5, Annex
VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Device
Regulation (EU) 2017/745 and the applicable
standards above.

The Declaration of Conformity is exclusively under the
sole responsibility of the manufacturer.

Signature:  Date: 2023-10-18

Position: GM

Place: Chengdu/China



Absorbent Paper Point Model

Model										Packaging form	
										Mixed Pack	Single Pack
02/10										/	200Pcs/box
02/15	02/20	02/25	02/30	02/35	02/40					02/10~02/40: 200Pcs/box	
02/45	02/50	02/55	02/60	02/70	02/80					02/45~02/80: 100Pcs/box	100Pcs/box
02/90	02/100	02/110	02/120	02/130	02/140					02/90~02/140: 100Pcs/box	
03/08	03/10									/	100Pcs/box
03/15	03/20	03/25	03/30	03/35	03/40					03/15~03/40: 100Pcs/box	
03/45	03/50	03/55	03/60	03/70	03/80					03/45~03/80: 100Pcs/box	
04/15	04/20	04/25	04/30	04/35	04/40					04/15~04/40: 100Pcs/box	100Pcs/box
04/45	04/50	04/55	04/60	04/70	04/80					04/45~04/80: 100Pcs/box	
05/15	05/20	05/25	05/30	05/35	05/40					05/15~05/40: 100Pcs/box	100Pcs/box
05/45	05/50	05/55	05/60	05/70	05/80					05/45~05/80: 100Pcs/box	
06/15	06/20	06/25	06/30	06/35	06/40					06/15~06/40: 100Pcs/box	100Pcs/box
06/45	06/50	06/55	06/60	06/70	06/80					06/45~06/80: 100Pcs/box	
F1	F2	F3	F4	F5						F1~F3: 100Pcs/box	100Pcs/box
										F1~F5: 100Pcs/box	
XF	FF	MF	F	FM	M	ML	L	XL		/	100Pcs/box