EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Manufacturer Name :	**Suzhou Pac-Dent Technology Co.,Ltd.**
Manufacturer Address:	**18, Yuanqi Road, Suzhou City, Jiangsu 215133, China**
:	
SRN:	**CN-MF-000021642**

We declare under our sole responsibility that /

the medical device:	**Apical Negative Pressure Irrigation and Activation Kits**
Model	**9542SIVC、9542EIVC、954235G、954250Y、9542SC、9542EC 9542ACT、9542LTA、9542ST、9542R、954101、954102**
of class:	**Class** Ⅰ **Annex Ⅷ, Rule 5**
Basis UDI-DI	**Introduction kit: 697316311ANPIAK00001C9;** **Refill kit: 697316311ANPIAK00002CB**

EU authorised representative	**Llins Service & Consulting GmbH**
Address:	**Obere Seegasse 34/2,69124,**
	Heidelberg, Germany
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According to Annex Ⅸ of MDR

meets the provisions of the European Medical Device Regulation 2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

We are exclusively responsible for the declaration of conformity

Conformity assessment procedure:	**uropean Medical Device Regulation 2017/745** **Annex** Ⅸ

Suzhou 2023.9.20
Place, date

Management Rep
Name and function