

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **United Dental Changzhou
No.9, Changyang Rd., Wujin District, Changzhou, 213145,
Jiangsu, P.R. China**

Trade name or mark: /



Single Registration No: /

EC Authorized Representative: / **Caretechion GmbH
Niederrheinstr. 71,
40474 Duesseldorf, Germany**

We declare under our sole responsibility that

Name of the medical device: / **Dental Irrigation Needles
Model: See Annex 1**

Product code: / **EMDN code: A010602**

Intended purpose: / **The Dental Irrigation Needles are used to remove debris or
debris in the oral cavity.**

Basic UDI-DI: / **697312285UDGIN0015C**

of class: / **Rule5, Class I**

According to annex VIII of Regulation (EU) 2017/745 /

Conformity assessment procedure: / **Declare the conformity of the abovementioned products by
issuing this EU Declaration of Conformity after drawing up the
technical documentation set out in Annexes II and III of
Regulation (EU) 2017/745 /
according to Article 52(7) of Regulation (EU) 2017/745 /**

We, the manufacturer, hereby declare under our sole responsibility that the abovementioned products meet the provisions of the Medical Device Regulation (EU) 2017/745. All supporting documents are retained under the premises of the manufacturer.

CHANGZHOU, 2021-08-18

Ort, Datum / Place, date /

Hao Mingjie

General Manager

A handwritten signature in black ink, appearing to read '郝铭洁' (Hao Mingjie), is written over a horizontal line.

Annex 1 Model list

No.	Device Model	No.	Device Model
1.	ORN-23G-22-1-S-S	65.	ORN-23G-22-1-S-N
2.	ORN-25G-22-1-S-S	66.	ORN-25G-22-1-S-N
3.	ORN-27G-22-1-S-S	67.	ORN-27G-22-1-S-N
4.	ORN-30G-22-1-S-S	68.	ORN-30G-22-1-S-N
5.	ORN-23G-26-1-S-S	69.	ORN-23G-26-1-S-N
6.	ORN-25G-26-1-S-S	70.	ORN-25G-26-1-S-N
7.	ORN-27G-26-1-S-S	71.	ORN-27G-26-1-S-N
8.	ORN-30G-26-1-S-S	72.	ORN-30G-26-1-S-N
9.	ORN-23G-22-1-S-M-S	73.	ORN-23G-22-1-S-M-N
10.	ORN-25G-22-1-S-M-S	74.	ORN-25G-22-1-S-M-N
11.	ORN-27G-22-1-S-M-S	75.	ORN-27G-22-1-S-M-N
12.	ORN-30G-22-1-S-M-S	76.	ORN-30G-22-1-S-M-N
13.	ORN-23G-26-1-S-M-S	77.	ORN-23G-26-1-S-M-N
14.	ORN-25G-26-1-S-M-S	78.	ORN-25G-26-1-S-M-N
15.	ORN-27G-26-1-S-M-S	79.	ORN-27G-26-1-S-M-N
16.	ORN-30G-26-1-S-M-S	80.	ORN-30G-26-1-S-M-N
17.	ORN-23G-22-2-S-S	81.	ORN-23G-22-2-S-N
18.	ORN-25G-22-2-S-S	82.	ORN-25G-22-2-S-N
19.	ORN-27G-22-2-S-S	83.	ORN-27G-22-2-S-N
20.	ORN-30G-22-2-S-S	84.	ORN-30G-22-2-S-N
21.	ORN-23G--26-2-S-S	85.	ORN-23G-26-2-S-N
22.	ORN-25G-26-2-S-S	86.	ORN-25G-26-2-S-N
23.	ORN-27G-26-2-S-S	87.	ORN-27G-26-2-S-N
24.	ORN-30G-26-2-S-S	88.	ORN-30G-26-2-S-N
25.	ORN-23G-22-2-S-M-S	89.	ORN-23G-22-2-S-M-N
26.	ORN-25G-22-2-S-M-S	90.	ORN-25G-22-2-S-M-N
27.	ORN-27G-22-2-S-M-S	91.	ORN-27G-22-2-S-M-N
28.	ORN-30G-22-2-S-M-S	92.	ORN-30G-22-2-S-M-N
29.	ORN-23G-26-2-S-M-S	93.	ORN-23G-26-2-S-M-N
30.	ORN-25G-26-2-S-M-S	94.	ORN-25G-26-2-S-M-N
31.	ORN-27G-26-2-S-M-S	95.	ORN-27G-26-2-S-M-N
32.	ORN-30G-26-2-S-M-S	96.	ORN-30G-26-2-S-M-N
33.	ORN-23G-22-3-B-S	97.	ORN-23G-22-3-B-N
34.	ORN-25G-22-3-B-S	98.	ORN-25G-22-3-B-N
35.	ORN-27G-22-3-B-S	99.	ORN-27G-22-3-B-N
36.	ORN-30G-22-3-B-S	100.	ORN-30G-22-3-B-N
37.	ORN-23G-26-3-B-S	101.	ORN-23G-26-3-B-N
38.	ORN-25G-26-3-B-S	102.	ORN-25G-26-3-B-N
39.	ORN-27G-26-3-B-S	103.	ORN-27G-26-3-B-N
40.	ORN-30G-26-3-B-S	104.	ORN-30G-26-3-B-N
41.	ORN-23G-22-3-B-M-S	105.	ORN-23G-22-3-B-M-N
42.	ORN-25G-22-3-B-M-S	106.	ORN-25G-22-3-B-M-N
43.	ORN-27G-22-3-B-M-S	107.	ORN-27G-22-3-B-M-N
44.	ORN-30G-22-3-B-M-S	108.	ORN-30G-22-3-B-M-N
45.	ORN-23G-26-3-B-M-S	109.	ORN-23G-26-3-B-M-N
46.	ORN-25G-26-3-B-M-S	110.	ORN-25G-26-3-B-M-N
47.	ORN-27G-26-3-B-M-S	111.	ORN-27G-26-3-B-M-N
48.	ORN-30G-26-3-B-M-S	112.	ORN-30G-26-3-B-M-N

49.	ORN-23G-22-2-B-S	113.	ORN-23G-22-2-B-N
50.	ORN-25G-22-2-B-S	114.	ORN-25G-22-2-B-N
51.	ORN-27G-22-2-B-S	115.	ORN-27G-22-2-B-N
52.	ORN-30G-22-2-B-S	116.	ORN-30G-22-2-B-N
53.	ORN-23G-26-2-B-S	117.	ORN-23G-26-2-B-N
54.	ORN-25G-26-2-B-S	118.	ORN-25G-26-2-B-N
55.	ORN-27G-26-2-B-S	119.	ORN-27G-26-2-B-N
56.	ORN-30G-26-2-B-S	120.	ORN-30G-26-2-B-N
57.	ORN-23G-22-2-B-M-S	121.	ORN-23G-22-2-B-M-N
58.	ORN-25G-22-2-B-M-S	122.	ORN-25G-22-2-B-M-N
59.	ORN-27G-22-2-B-M-S	123.	ORN-27G-22-2-B-M-N
60.	ORN-30G-22-2-B-M-S	124.	ORN-30G-22-2-B-M-N
61.	ORN-23G-26-2-B-M-S	125.	ORN-23G-26-2-B-M-N
62.	ORN-25G-26-2-B-M-S	126.	ORN-25G-26-2-B-M-N
63.	ORN-27G-26-2-B-M-S	127.	ORN-27G-26-2-B-M-N
64.	ORN-30G-26-2-B-M-S	128.	ORN-30G-26-2-B-M-N