EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Name: Shanghai Greeloy Industry Co., Ltd. Add: 6 Building, Songhuang Road 999, Qingpu District, 201706. Shanghai, China
SRN:	CN-MF-000035370
European Representative:	Name: Prolinx GmbH Add: Brehmstr. 56, 40239, Duesseldorf , Germany
SRN:	DE-AR-000005129
Product Name:	Dental Suction Unit
Trade Name:	/
Basic UDI-DI :	697654080GS44
Product Models:	GS-01 GS-02 GS-03 GS-03F GS-05 GS-10 GS-20 GS-30 GS-50 GS-M300 GS-M400 GS-E1000 GS-DC100
Classification acc. to MDR Ax. VIII:	Class I, Rule13
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex I, II Part A
Applied Common Specification/ standard:	EN ISO 13485:2016 EN ISO 15223-1:2021 EN ISO 14971:2019/A11:2021 EN ISO 20417:2021 IEC 60601-1:2005 +A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 EN 62366-1: 2015+A1:2020 IEC60601-1-6: 2010+A1: 2013+A2: 2020

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Place of Issue: Shanghai, China

Date of Issue: October 31, 2024

Signature:

Name: Mr.Mingbao Lu

Position: General Manager