EC Declaration of Conformity

According to REGULATION (EU) 2017/745

Class I *Medical Device*

Manufacturer:	Guangdong Launca Medical Device Technology Co., Ltd.
SRN:	CN-MF-000009649
Address:	Room 901-908 and 914-916, Building 5, No.1 Yanfa Road，Songshan Lake Park,Dongguan,Guangdong,523808,China
EC Representative:	Wellkang Ltd Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland, UK

We, the manufacturer, declare under our sole responsibility that：

the medical device(s)	Product Name	Type/model, identification of product allowing traceability (Where applicable)
	Intraoral Scanner	**DL-300，DL-300P**
of class	According to annex Ⅷ of Regulation(EU)2017/745, Rule 5 and Rule 13	**Class I** Medical Device
Basic UDI-DI	697374720DL300EL	

is/are in conformity with the relevant provisions and requirements of Regulation(EU)2017/745.

Applied harmonised standards, national standards or other normative documents	EN ISO 13485:2016	EN ISO 15223-1:2016
	EN 1041:2008	EN 62133:2020
	EN ISO 14971:2019	EN 60601-1:2006+A12:2014+A2:2021
	EN ISO 7405:2008	EN 60601-1-2:2015+A1:2021
	EN ISO 10993-1: 2018	EN ISO 10993-5:2009
	EN ISO 10993-10:2013	EN 62304:2006+A1:2015
	EN ISO 17665-1:2006	EN 62366-1:2015+A1:2020

Conformity assessment procedure	Module A (EC Declaration of Conformity (Annex Ⅳ) + Technical Files)
Notified Body (name & number) Certificate & number	**NOT applicable**

Signed on: Mar.16, 2023 Place: Dongguan, Guangdong, China

Signature (on behalf of the manufacturer) 

Name of authorized signatory: Jian Lv

Position held in the company: General Manager