

EC DECLARATION OF CONFORMITY



Manufacturer: Foshan Modern Precision Dental Instruments Co., Ltd
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We declare under our sole responsibility that

Medical device name: Intra Oral Camera

Model: BR-505

Intended purpose: Is it intended for chairside use of oral health examinations. It provides digital color images of intraoral or extraoral anatomy through a camera and monitor or PC. Both still and video images can be captured and stored. It does not get into contact with any body parts and it is intended for use with protection covers.

Of class: I, according to (EU) 2017/745 Medical Device Regulation

Conformity assessment procedure: Article 19, Annex II and Annex III according to Regulation (EU) 2017/745.

Meets the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards EN ISO14971:2019, EN ISO 15223-1:2016, ISO10993-1:2018, EN ISO10993-5:2009, EN ISO10993-10:2010, EN 1041:2008+A1:2013, EN62366-1:2015 and its transpositions in national laws which apply to it.

PLACE, DATE OF DECLARATION: FOSHAN MODERN PRECISION DENTAL INSTRUMENTS CO., LTD

STAMP:



NAME: HUANG TINGHAO;

POSITION: GENERAL MANAGER;

DATE: 2022 01-18