

EC DECLARATION OF CONFORMITY



Manufacturer: Foshan Modern Precision Dental Instruments Co., Ltd
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Contact: 008675786690279 / admin@mdedental.com
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EU Representative: Caretechion GmbH
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SRN: DE-AR-000005946

We declare under our sole responsibility that

Medical device name: Dental Oil Lubricating Machine

Model: BR-808

Intended purpose: Is it intended for lubricating Air Driven Dental Instruments (high speed turbine, straight and angle handpieces, dental air-motor). It does not get into contact with any body parts and it is intended for use with dedicated lubricating oil

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