佛山市创昕医疗器械有限公司
FOSHAN CHUANGXIN MEDICAL APPARATUS CO.,LTD

Declaration of Conformity

CX-CX-TCF-03 A4

For the following products:

Integral Dental unit , CX-2305

Classification: Class IIa, rule 9 of Annex IX of MDD 93/42/EEC

Conformity: Assessment Route: Annex V of MDD 93/42/EEC

are hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC as amended by 2007/47/EC)

EN ISO 15223-1: 2016 Medical devices. Symbols to be used with medical device Labels, labelling and information to be supplied - Part 1: General requirements

EN1041:2008 Information supplied by the manufacturer of medical devices

EN 60601-1:2006+A1 :2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

MEDDEV 2.7.1 rev.4 Clinical evaluation: Guide for manufacturers and notified bodies

EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

EN 1640:2009 Dentitry — Medical devices for dentistry — Equipment

ISO 6875 :2011 Dentistry —— Patient Chair

Add: Eastern Industrial Development Zone,Xiadong Chongkou Pingliu Road, Guicheng Street,Nanhai District,Foshan City,Guangdong Province,China.
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ISO 7494-1-2004 Dentistry - Dental units - Part 1: General requirements and test methods

ISO 7494-2-2003 Dentistry - Dental units - Part 2: Water and air supply

EN ISO 9680-2014 - Dentistry - Operating lights (ISO 9680:2014)

EN 62304 :2015 Medical device software-software life-cycle processes

IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices

EN 80601-2-60-2015 Medical electrical equipment -- Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

The following manufacturer is responsible for making this declaration:

Company Name: FOSHAN CHUANGXIN MEDICAL APPARATUS CO.,LTD

Company Address: Eastern Industrial Development Zone , Xiadong Chongkou Pingliu Road , Guicheng Street, NanHai District, FoShan, China

EU Authorized Representative: Lotus NL B.V.
(Address: Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.)

EC Certificate information:
EC Certificate No.: FI15/07009 Production quality assurance system
This certificate is valid from 22 January 2019 until 3 December 2024

Notified Body (if consulted): SGS FIMKO OY
Code: 0598
Address: P.O.Box 30(Särkiniementie 3) 00211 HELSINKI Finland

(Legal Signature) G.M (Position/title) NOV 15, 2023 (Date)

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