# DECLARATION OF CONFORMITY

## TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993

## CONCERNING MEDICAL DEVICES

MANUFACTURER: KASO MEDICAL TECHNOLOGY CO., LTD
4TH FLOOR, BUILDING 2, DONGHUA INDUSTRY AREA,SHAKENG, LUOCUN, SHISHAN, NANHAI DISTRICT, FOSHAN CITY, GUANGDONG PROVINCE,CHINA

MEDICAL DEVICE: DENTAL UNIT
MODEL : KS-DLX301，KS-D106，KS-R3, KS-D213
CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 9
CONFORMITY ASSESSMENT ROUTE: ANNEX VII + V

WE, KASO MEDICAL TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTERNATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: EN ISO 15223-1:2016, EN ISO 9687:2015, EN 1041:2008, EN ISO 14971:2012, EN 1639:2009, EN 1640:2009, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 80601-2-60:2015, EN 62366-1:2015, EN ISO7494-1:2011, EN ISO7494-2:2015, EN ISO 6875:2011, EN ISO 9680:2014, EN ISO 10993-1:2009/AC:2010, EN 62304:2006 +A1-2015, EN ISO 11144:1996, EN ISO 7405:2018, ENISO 10993-1:2009/AC:2010, EN 62471:2008

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EC REP

EUROPEAN REPRESENTATIVE: LOTUS NL B.V.
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*(EC) CERTIFICATE(S):*

*FI20/07014*

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*SIGNATURE: NAME MR. YUXING LIU (GENERAL MANAGER)*