



EC Declaration of Conformity

Manufacturer: Guilin Kevin Peter Technology Co., Ltd.
North side of Linsu Rd, Lingui Town, Lingui Dist.,
Guilin, Guangxi 541100, P. R. China

SRN of Manufacturer: CF-MF-000022934

European Representative: MedNet EC-REP C llb GmbH
Borkstrasse 10,48163 Muenster,Germany

SRN of European Representative: DE-AR-000011194

Product Name: Intraoral Camera

Models: KP Cam,KP Cam Pro

Classification: I / Rule 13 (MDR, Annex VIII)

CND Code: Z11030402

Basic UDI-DI: 6975384339968

Conformity Assessment Route: Annex II, Annex III of (EU)2017/745, MDR



We, the manufacturer, declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, is exclusively responsible for the Declaration of Conformity.

General applicable regulations: Medical Device Regulation, (EU)2017/745.

Applied standards:

No.	Standard	No.	Standard
1	EN ISO 13485:2016	14	EN ISO 15223-1:2021
2	EN 62304:2006+A1:2015	15	EN 1041:2008+A1:2013
3	ISO 10993-1-2018	16	EN 62366-1:2015
4	ISO 10993-2:2022	17	MDR 2017/745
5	ISO 10993-5:2009	18	MDCG 2020-5
6	ISO 10993-10-2021	19	MDCG 2020-13
7	ISO 10993-23:2021	20	EN ISO 14971:2019



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Version: A

8	ISO 7405: 2018	21	MDCG 2023-3
9	MEDDEV 2.7/1 revision 4	22	MEDDEV 2.12/2
10	EN 60601-1:2006+A2:2021	23	MDCG 2020-7
11	EN 60601-1-2:2015+A1:2021	24	MDCG 2020-8
12	EN IEC 80601-2-60:2020	25	MDCG 2020-5
13	ISO 15223-1-2021	/	/

Name: Wei Kunsong

Position: PRRC

Location: Guilin, China

Signature:  2023.10.07

