EC Declaration of Conformity

Manufacturer:	**Guilin Kevin Peter Technology Co., Ltd.** North side of Linsu Rd, Lingui Town, Lingui Dist., Guilin, 541100, P. R. China
SRN of Manufacturer:	CF-MF-000022934
European Representative:	**MedNet EC-REP GmbH** Borkstrasse 10, 48163 Muenster, Germany
SRN of European Representative:	DE-AR-000000002
Product Name:	Intraoral Scanner
Models:	K-Scan,Smile Scan
Classification:	I / Rule 13 (MDR, Annex VIII)
CND Code:	Q010207
Basic UDI-DI:	697538433003MG
Conformity Assessment Route:	Annex II, Annex III of (EU)2017/745, MDR

We herewith 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 are 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	16	EN 1041:2008+A1:2013
2	EN 62304:2006+A1:2015	17	EN 62366-1:2015
3	ISO 10993-1-2018	18	MDR 2017/745
4	ISO 10993-2:2022	19	EN ISO 17664:2017
5	ISO 10993-5:2009	20	EN ISO 17665-1:2006
6	ISO 10993-10-2021	21	AAMI TIR30-2011-A
7	ISO 10993-23:2021	22	MDCG 2020-5
8	ISO 7405: 2018	23	MDCG 2020-13

9	MEDDEV 2.7/1 revision 4	24	EN ISO 14971:2019
10	EN 60601-1:2006+A2:2021	25	MEDDEV 2.12
11	EN 60601-1-2:2015+A1:2021	26	MEDDEV 2.12/2
12	EN IEC 80601-2-60:2020	27	MDCG 2020-7
13	ISO 20896-1 : 2019	28	MDCG 2020-8
14	ISO 15223-1-2021	29	MDCG 2020-5
15	EN ISO 15223-1:2021	30	EN ISO 20417:2021

Name: Wei Kunsong

Position: PRRC

Location: Guilin, China

Signature: