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EC Declaration of Conformity

Manufacture	**Guilin Kevin Peter Technology Co., Ltd.** Standard workshops, F2-F3, BLDG 4, HUAWEI INFO ECO IND COOP ZONE, North side of Linsu Rd, Lingui Town, Lingui Dist., Guilin, 541104, P. R. China SRN:CF-MF-000022934
European Representative:	**MedNet EC-REP GmbH** **Borkstrasse 10·48163 Muenster Germany** SRN:DE-AR-000000002
Product Name:	**Surgical Microscope**
Model	**iSee 9000**
Brands	/

Classification (MDR, Annex VIII): Class I / Rule 13, (MDR, Annex VIII)
GMDN Code: 32439
EMDN Code: Z12011101
Basic UDI - DI: 697538433001MC
Conformity Assessment Route: Annex II, Annex III of (EU)2017/745, MDR

we, the manufacturer, herewith declare on our solo responsibility 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, are exclusively responsible for the Declaration of Conformity.

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

Applied standards

EN 60601-1-2006+A11: 2011+A11:2013+A12:2014
EN 60601-1-2-2015,
EN ISO 13485-2016
EN ISO 15223-2021
EN ISO 20417-2021,
EN ISO 14971:2019,
IEC 62366-1:2020.

Place, Date of Issue

Name: 魏坤松（Wei Kunsong）
Position: PRRC
Location: Guilin, China
Signature: 2022.7.21