

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

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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,

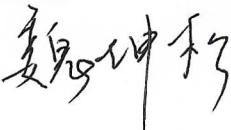
EN ISO 14971:2019,

IEC 62366-1:2020.

Place, Date of Issue


Name: 魏坤松 (Wei Kinsong)
Position: PRRC
Location: Guilin, China

Signature:

 2022.7.21