

DECLARATION OF CONFORMITY

Manufacturer:

Science & Engineering Center Scanner, Ltd.
122/1 Smilianska st., 18019 Cherkasy, Ukraine

EC-Representative:

Medicor-Pol Zaklad Techniki Medycznej Sp. Z o.o
233 Kilinskiego st., 93-133 Lodz, Poland

Product Category:

Colposcope

Model/Type:

MK-300

Classification of the device:

Class I, Medical Device Regulation 2017/745

Identification of Notified Body:

**Quality Austria-Trainings, Zertifizierungs und
Begutachtungs GmbH.**
Notified Body EC Code: 1346

Certificates:

CERTIFICATE ISO 13485:2016
Registration No.: 00223/0

Applicable standards:

ISO 13485:2016;
EN ISO 14971:2012; IEC 62366:2015;
EN 60601-1-1:2001, IDT; IEC 60601-1-6:2010, IDT;
EN 60601-1-2:2015, IDT; IEC 60601-1-2:2014, IDT;
EN 61000-4-2:2009, IDT; IEC 61000-4-2:2008, IDT;
EN 61000-4-3:2006, IDT; IEC 61000-4-3:2006, IDT;
EN 61000-4-4:2012, IDT; IEC 61000-4-4:2012, IDT;
EN 61000-4-5:2014, IDT; IEC 61000-4-5:2014, IDT;
EN 61000-4-6:2014, IDT; IEC 61000-4-6:2013, IDT;
EN 61000-4-11:2004, IDT; IEC 61000-4-11:2004, IDT.

We, the manufacture hereby declare
that the above-mentioned device comply with the
relevant provisions of EU Council Regulation 2017/745.

Cherkasy 2021/08/23

Renat SINGATULLIN
Director

Fedor YAKUBCHUK
Quality Manager

