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## 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-200**

**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 2021/08/25**

Renat SINGATULLIN  
Director

Fedor YAKUBCHUK  
Quality Manager

