EU DECLARATION OF CONFORMITY

Declared under sole responsibility of the producer

Under Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices,

Manufacturer: Kettex Development s.r.o
Address: Na pěšině 465/6, Praha 8, 184 00, Česká republika
ID No: 3267016

Product Identification Data
Name: FULL HD ENDOSCOPY CAM KX-01-OR
Basic UDI-DI: 8594200760CAMKX01OUK

The manufacturer **declares on his sole responsibility** that the characteristics of the above-mentioned medical device meet all requirements in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council, and that the medical device is safe, effective and appropriate for the provision of healthcare for its intended purpose of use. The manufacturer further declares that it has taken measures to ensure the conformity of the medical device placed on the market with the essential requirements and the manufacturer's technical documentation.

Designated use:
The intended purpose of the Full HD Endoscopy Cam KX-01-OR video endoscopic medical device is to digitize the image visible in the eyepiece of the endoscope and then display it on the PC. The medical device allows image manipulation for better contrast and visibility of structures. The device is intended for both diagnostic and surgical use.

Risc class: I, non-sterile, non-measuring

Harmonised standards applied: ČSN EN 1041 + A1:2014, ČSN EN ISO 14971:2020, ČSN EN ISO 15223-1:2017, ČSN EN ISO 10993-1:2010, ČSN EN 60601-1 ed. 2:2007 + A1:2014 + A12:2015, ČSN EN 60601-1-2:2016, ČSN EN 60601-2-18 ed. 2:2016, ČSN EN 62366-1:2019, ČSN EN 60601-1- 6 ed. 3:2010 + A1:2015

Done at Prague 10. 2. 2021

RNDr. Filip Krolupper, PhD
CEO of Kettex Development s.r.o.