EU DECLARATION OF CONFORMITY

issued under the sole responsibility of the manufacturer

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

Manufacturer: Kettex Development sro
Registered office: Na pěšině 465/6, Prague 8, 184 00, Czech Republic
ID: 3267016
Actor ID/SRN: CZ-MF-000004085

Product identification data
Name: FULL HD ENDOSCOPY CAM KX-02
Base UDI-DI: 8594200760CAMKX-02S9

The manufacturer **declares** under its sole responsibility that the characteristics of the above-mentioned medical device meet all the requirements in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council, and that this medical device is safe, effective and suitable for the provision of healthcare for its intended purpose. 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.

Intended use:
The intended purpose of the Full HD Endoscopy Cam KX-02 video-endoscopic medical device is to digitize the image visible in the eyepiece of the endoscope and its subsequent display on a PC. The medical device allows for image manipulation for better contrast and visibility of structures. The device is intended for both diagnostic purposes and use during operations.

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

Standards used : ČSN EN ISO 20417:2021, ČSN EN ISO 14971:2020/A11:2022, ČSN EN ISO 15223-1:2022, ČSN EN ISO 10993-1:2021, ČSN EN 60601-1:2007 +A11:2012 +A1:2014 + A12:2015 + A2:2022 + A13:2025 , ČSN EN 60601-1-2:2016/A1:2021, ČSN EN 60601-2-18 ed. 2:2016, ČSN EN 62366-1:2019/A1:2021, ČSN EN 60601-1- 6 ed. 3:2010 + A1:2015/A2:2021

In Prague on 15. 5. 2025

RNDr. Filip Krolupper, PhD
Managing Director of Kettex Development sro