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: KETTEX EVISION – SOFTWARE
Basic UDI-DI: 8594200760000SWEND5L

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:
Kettex EVision Medical Device — Software is used to display, store and capture a digitized image in the form of images or videos from a compatible endoscopic camera.

The medical device allows image manipulation for better contrast and visibility of structures.

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

Harmonised standards applied: ČSN EN 1041:2008 + A1:2013, ČSN EN ISO 14971:2012, ČSN EN ISO 15223-1:2017, ČSN EN 62366-1:2019, ČSN EN 62304:2007

Done at Prague 5.10.2020

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