Novocam Medical Innovations Oy

# EU Declaration of Conformity

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| **Manufacturer Name** | Novocam Medical Innovations Oy |
| **SRN** | FI-MF-000011728 |
| **Brands** | futudent<br>novoCam |
| **Manufacturers Address**<br>**Zip and city**<br>**Country**<br>**VAT code** | Pasilanraitio 5B<br>00240 Helsinki<br>Finland<br>FI2429513-0 |
| **Email**<br>**Phone** | info@futudent.com<br>+358 50 388 0008 |

**Applicable to Devices:**

| UDI-DI | Tradename | Model / Reference |
|---|---|---|
| 06429810664020 | microCam XS | MCCX |
| 06429810664013 | proCam XS | PRCX |
| 06429810664006 | smartCam | SMCS |
| 06429810664051 | scopeCam | CMPX |
| 06429810664037 | proCam | PRCG |
| 06429810664044 | eduCam | EDUS |

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| **Intended Use:** | These apparatuses are intended by the manufacturer to be used by qualified healthcare professionals to capture videos and pictures during dental and medical treatments for the purpose of documentation, providing additional information for diagnosis, following and evaluating changes of medical conditions and for educational purposes in dental and medical fields. |
| **MDR 2017/745 Risk:** | Class I |
| **Specifications Applied:** | ISO13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes.<br>IEC 60601-1:2005 + AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |

This EU declaration of conformity is issued under the sole responsibility of Novocam Medical Innovations Oy. We hereby declare that the medical device(s) above meet the provision of the Regulation (EU) MDR 2017/745 for medical device, and for the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive 2011/65/EU and thus the CE marking can be affixed to the device. All supporting documentation is retained at the premises of the manufacturer.

Lars Kåhre

CEO

Place and date of issue:

Helsinki 09 January 2023