

Certificate of Conformity

Manufacturer Name Novocam Medical Innovations Oy

SRN FI-MF-000011728

Brands futudent
novoCam

Manufacturers Address Pasilanraito 5B

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Country Finland

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Applicable to Devices	UDI-DI	Tradename	Model / Reference
with Basic UDI-DI	06429810664020	microCam XS	MCCX
6429810664MCI0000000QV:	06429810664013	proCam XS	PRCX
	06429810664006	smartCam	SMCS
	06429810664051	scopeCam	CMPX
	06429810664037	proCam	PRCG
	06429810664044	eduCam	EDUS

GMDN Code 35580 Camera, diagnostic imaging, multi-format

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

Standards for Product Safety Compliance: ISO 13485:2016 Medical devices. Quality management systems.
Requirements for regulatory purposes.
IEC 60601-1:2005 + AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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 and complies with the requirements of MDR 2017/745 Annex IV. 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.

Signature:

Kirsty Happonen, Quality Manager



Place and date of issue:

Helsinki 02 October 2023