



EU DECLARATION OF CONFORMITY

Manufacturer name and address:

Akino Medical Pte Ltd

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SRN (Single Registration Number):

SG-MF-000033198

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We, Akino Medical Pte Ltd, hereby declare under our sole responsibility that the devices listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

This Declaration is applicable to the devices listed in the Annex to the Declaration of Conformity. Basic UDI-DI, risk class and classification rules according to Annex VIII of REGULATION (EU) 2017/745 and other relevant data, e.g., intended purpose, catalogue number are provided in the Annex to the Declaration of Conformity.

The conformity assessment procedure has been performed following Art 19 and Art 52 (7), and technical documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

EN ISO 13485 2016 + A1: 2021, EN ISO 14971: 2019 + A 11: 2021, EN ISO 15223-1: 2016, EN ISO 1041: 2008 + A1: 2013

Singapore (20/02/23)

Issue place and date

Authorized Signatory



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Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ EMDN code
1	Erato 1 Camera	2D1C/1H.20HD	CMOS sensor-based high-definition medical endoscopy camera systems. Erato series cameras are class I products and should be used only with compatible endoscopes. The camera system does not come in contact with the patient.	Erato series cameras are to be used for minimal invasive surgeries along with endoscopes. Surgical procedures performed with it are Laparoscopy, Hysteroscopy, Urology Endoscopy, ENT Endoscopy, Arthroscopy.	I	Rule 1	++G307AK0 1ECAMAZ	18034/ Z120204 05
2	Erato 2 Camera	2D2C/1H.20HD	CMOS sensor-based high-definition medical endoscopy camera systems. Erato series cameras	Erato series cameras are to be used for minimal invasive surgeries along with endoscopes. Surgical procedures	I	Rule 1	++G307AK0 1ECAMAZ	18034/ Z120204 05





			are class I products and should be used only with compatible endoscopes. The camera system does not come in contact with the patient.	performed with it are Laparoscopy, Hysteroscopy, Urology Endoscopy, ENT Endoscopy, Arthroscopy.				
3	Erato 3 Camera	2D3C/3H.60HD	CMOS sensor-based high-definition medical endoscopy camera systems. Erato series cameras are class I products and should be used only with compatible endoscopes. The camera system does not come in contact with the patient.	Erato series cameras are to be used for minimal invasive surgeries along with endoscopes. Surgical procedures performed with it are Laparoscopy, Hysteroscopy, Urology Endoscopy, ENT Endoscopy, Arthroscopy.	I	Rule 1	++G307AK0 1ECAMAZ	18034/ Z120204 05
4	Erato 4 Camera	2D4C/4H.804K	CMOS sensor-based 4K medical endoscopy camera systems. Erato series cameras are class I products and should be used only with compatible	Erato series cameras are to be used for minimal invasive surgeries along with endoscopes. Surgical procedures performed with it are Laparoscopy, Hysteroscopy, Urology Endoscopy,	I	Rule 1	++G307AK0 1ECAMAZ	18034/ Z120204 05





			endoscopes. The camera system does not come in contact with the patient.	ENT Endoscopy, Arthroscopy.				
5	Staro 2	LEDS.120U	The light is produced by a high-power white Light-emitting diode (LED) and concentrated on the fiber output port	The Staro 2 light source is used for illumination of a surgical field during medical procedures by connecting a fiber optic cable to the endoscope.	I	Rule 1	++G307AK0 3MONTGY	34540/ Z120204 02
6	Surgical display monitor	MO2D.2727	27-inch High-resolution monitors with enhanced brightness and wider view angles.	Akino Surgical Display monitors are intended for visualization of anatomical image/ video signals sent by the Endoscopy camera system.	I	Rule 1	++G307AK0 3MONTGY	56654/ Z120204 80
7	Surgical display monitor	MO2D.2424	24-inch High-resolution monitors with enhanced brightness and wider view angles.	Akino Surgical Display monitors are intended for visualization of anatomical image/ video signals sent by the Endoscopy camera system.	I	Rule 1	++G307AK0 3MONTGY	56654/ Z120204 80
8	Surgical display monitor	MO2D.274K	27-inch 4K High-resolution monitors with enhanced brightness and wider view angles.	Akino Surgical Display monitors are intended for visualization of anatomical image/ video signals sent by the Endoscopy camera system.	I	Rule 1	++G307AK0 3MONTGY	56654/ Z120204 80





9	Surgical display monitor	M02D.324K	32-inch 4K High-resolution monitors with enhanced brightness and wider view angles.	Akino Surgical Display monitors are intended for visualization of anatomical image/ video signals sent by the Endoscopy camera system.	I	Rule 1	++G307AK03MONTGY	56654/Z12020480
10	Flexible Nasolaryngoscope	2034.3000F	Flexible Nasolaryngoscope used to visualise body cavities	Flexible Nasolaryngoscope is used to visualize body cavities. They were developed exclusively for the inspection of nasal cavities, the pharynx and the larynx (up to the vocal folds).	I	Rule 5	++G307AK10NASOEJ	35204/Z12029099
11	Laryngoscope	2060.1670S	Rigid scope used to visualize body cavities	Laryngoscopes are used for surgical and diagnostic procedures for examination and treatment of the larynx. This scope is inserted through the mouth till the larynx, a part of the throat.	I	Rule 5	++G307AK11LARYEY	36645/Z12029099

