

DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/745, we

EMOS Technology GmbH

Gewerbestrasse 10

D - 88636 Illmensee

SRN: DE-MF-000006428

declare under our responsibility that the devices mentioned in the attached device list meet the General Safety and Performance Requirements as defined in Annex I of MDR 2017/745.

This Declaration of Conformity is issued according to Annex IV Regulation (EU) 2017/745.

Device Category: Imaging Systems
Classification: Risk Class I, per Annex VIII of Regulation (EU) 2017/745
Conformity Assessment: Per Annex II and III of Regulation (EU) 2017/745
EU Notified Body: mdc medical device certification GmbH
Kriegerstraße 6, 70191 Stuttgart,
Germany

A complete list of the standards, directives, and regulations applied is available upon request.

We hereby declare that the medical devices listed herein comply with Regulation (EU) 2017/745 and with other applicable legislation for medical devices. This declaration is supported by the ISO 13485 Quality Management System certification issued by mdc medical device certification GmbH. The devices may therefore be placed on the Market labelled with



This Declaration is valid for all devices listed in the Device List below until 31.12.2030

City: Illmensee

Date: 29.01.2026

Michael Flickinger
CEO

Eugen Brikow
Qualified Person (PRRC)

Generic Device Group	Camera unit, endoscopy		
Intended Use	The camera systems are intended for capturing and displaying (on connected monitors) the surgical site (operative field) during minimally invasive surgical procedures (endoscopy).		
Risk Class	I	Rule	13
Basic-Udi	42506288Z12020405KAMUJ	GMDN No.	35958
EMDN No.	Z12020405	UMDNS No.	15-748
Item No.: CU1HDER, CU1HDE, CU3HDR, CU3HD, CU4KR, CU4K, CUUSB <i>(previous BUCK HD CAM)</i>			

Generic Device Group	Camera and light source system unit, endoscopy		
Intended Use	Combined system for illumination and recording as well as displaying the surgical site (operating field) during minimally invasive surgical procedures.		
Risk Class	I	Rule	10
Basic-Udi	42506288Z12020405KLQVT	GMDN No.	34540
EMDN No.	Z12020405	UMDNS No.	15-748
Item No.: CUCOMPR			

Generic Device Group	Camera head, endoscopy		
Intended Use	The camera head is intended to be used in combination with a camera unit to capture and transmit high-resolution images during endoscopic procedures.		
Risk Class	I	Rule	13
Basic-Udi	42506288Z12020499KAKYD	GMDN No.	35958
EMDN No.	Z12020499	UMDNS No.	15-748
Item No.: CH1HDE, CH1HD, CH3HD, CH4K			

Generic Device Group	Camera head adapter, reusable		
Intended Use	The device is intended to connect a camera head to a non-video endoscope (rigid or flexible).		
Risk Class	I	Rule	1
Basic-Udi	42506288Z12029099TVA6D	GMDN No.	36292
EMDN No.	Z12020499	UMDNS No.	11-726
Item No.: TA140H, TA140UH, TA1530ZH, TA1535Z, TA180H, TA180UH, TA220H, TA220UH, TA250H, TA250IR, TA250UH, TA280H, TA280UH, TA350UH			

Generic Device Group	Endoscope light source unit		
Intended Use	Base unit for generating/providing light to illuminate the surgical site (operative field) during minimally invasive surgical procedures (endoscopy).		
Risk Class	I	Rule	10
Basic-Udi	42506288Z12020402FLSUH	GMDN No.	35158
EMDN No.	Z12020402	UMDNS No.	12-340
Item No.: LS2500LED, LS3000LED			

Generic Device Group	Mobile LED Endoscope light source		
Intended Use	The Light Source is intended for the generation of light during endoscopic diagnostic procedures.		
Risk Class	I	Rule	10
Basic-Udi	42506288Z12020402ZUBXE	GMDN No.	35906
EMDN No.	Z12020402	UMDNS No.	12-340
Item No.: 200.02531.02, 200.02531.03			

Generic Device Group	Mobile LED Endoscope light source adapter, reusable		
Intended Use	The device is intended to be connected on EMOS mobile LED Endoscope light sources		
Risk Class	I	Rule	1
Basic-Udi	42506288Z12020499MPZ35	GMDN No.	37089
EMDN No.	Z12020499	UMDNS No.	11-726
Item No.: 370.00362.00			

Generic Device Group	Fiber optic cable, reusable		
Intended Use	The device is intended to transport cold light from a light source to an endoscope		
Risk Class	I	Rule	1
Basic-Udi	42506288Z12020485LKAXM	GMDN No.	35507
EMDN No.	Z12020485	UMDNS No.	15-308
Item No.: LC351800, LC351800S, LC352300, LC353000, LC481800, LC482300, LC483000, LC351800B, LC352300B, LC353000B, LC481800B, LC482300B, LC483000B			

Generic Device Group	Fiber optic cable adapter, reusable		
Intended Use	The device is intended to be connected to a fiber optic cable, to permit the connection of the cable to a light source or an endoscope.		
Risk Class	I	Rule	1
Basic-Udi	42506288Z12020499LSAZL	GMDN No.	37089
EMDN No.	Z12020499	UMDNS No.	11-726
Item No.: LC10, LC1P, LC1S, LC1W, LC0S0, LC0W			