EU DECLARATION OF CONFORMITY

(Annex IV of regulation 2017/745)

SURGIRIS
SMART VISION

I undersigned Mr Denis PAPIN, General Manager of SURGIRIS SAS whose headquarters are located at 80 rue de la Gare 59170 CROIX France, registered on manufacturer number : **FR-MF-000004556**, certify and declare on my sole responsibility that the medical devices following (basic UDI-DI : 3701502600033C).

STATION ALL IN ONE				
Model	**Type**	**Reference**	**Designation**	**UDI-DI**
STATION AIO	STATION AIO 32	VID-STA-32E01-0001	STATION ALL IN ONE 32" FULL HD VM 4K SDI IN WALL VERSION	3760194370033
		VID-STA-32E02-0001	STATION ALL IN ONE 32" FULL HD VM 4K HDMI IN WALL VERSION	3760194370040
	STATION AIO 55	VID-STA-55E01-0001	STATION ALL IN ONE 55" 4K VM 4K SDI IN WALL VERSION	3760194370071
		VID-STA-55E02-0001	STATION ALL IN ONE 55" 4K VM 4K HDMI IN WALL VERSION	3760194370088

STATION MONITOR				
Model	**Type**	**Reference**	**Designation**	**UDI-DI**
STATION MONITEUR	STATION MONITEUR 55	VID-STA-55E00-0001	STATION MONITOR 55" 4K IN WALL VERSION	3760194370118

ACCESSORIES			
Reference	**Designation**	**Reference**	**Designation**
VID-ACS-03-00-0001	AUDIO BASE SET FOR STATION ALL IN ONE	VID-ACS-03-00-0002	SET OF 2 CEILING SPEAKERS + CABLE LSP 2X15M
VID-ACS-03-03-0001	BLUETOOTH HEADSET SET	VID-ACS-07-00-0001	FULL HD PTZ IP CAMERA
VID-ACS-08-00-0008	AZERTY MEDICAL KEYBOARD FOR STATION ALL IN ONE	VID-ACS-08-00-0009	QWERTY MEDICAL KEYBOARD FOR STATION ALL IN ONE
VID-ACS-08-00-0010	AZERTY MEDICAL KEYBOARD	VID-ACS-08-00-0011	QWERTY MEDICAL KEYBOARD
VID-ACS-08-00-0003	WIRED SCANNER	VID-ACS-08-00-0004	WIRELESS SCANNER
VID-ACS-08-00-0001	ADDITIONAL MEMORY FOR 1TB HDD HARD DRIVE	VID-ACS-08-04-0001	DOUBLE WIRED PEDAL WITH XLR CABLE 5M

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ANNEX IV OF REGULATION 2017/745

These medical devices are class I medical devices as defined by Annex VIII of the Regulation (EU) 2017/745

These medical devices are in conformity and comply to the essential requirements of the regulation (EU) 2017/745, as well as the main technical standards concerning surgical lightings (NF EN 60601-1, NF EN 60601-1-2). They also comply with any other current technical and safety standards.

On the other hand, these medical devices are in conformity with the directive 2011/65/UE on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and these successive adaptations.

I undertake to enforce all the related regulatory and standards developments that have to be applied on these devices.

DONE AT CROIX, ON THE 18/07/2023

DENIS PAPIN
GENERAL MANAGER

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