

DECLARATION DE CONFORMITE UE

Annexe IV du règlement
2017/745



EU DECLARATION OF CONFORMITY

Annex IV of regulation 2017/745

Je soussigné Monsieur Denis PAPIN, Directeur Général de SURGIRIS SAS dont le siège est situé 80 rue de la gare 59170 CROIX France, enregistré sur le numéro d'enregistrement unique fabricant : FR-MF-000004556, assure et déclare sous ma seule responsabilité que les dispositifs médicaux suivants (IUD-ID de base : 3701502600033C).

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				
Modèle / Model	Type	Référence / Reference	Désignation française	English designation
STATION AIO	STATION AIO 32	VID-STA-32E01-0001	STATION ALL IN ONE 32" FULL HD VM 4K SDI VERSION ENCASTREE	STATION ALL IN ONE 32" FULL HD VM 4K SDI IN WALL VERSION
		VID-STA-32E02-0001	STATION ALL IN ONE 32" FULL HD VM 4K HDMI VERSION ENCASTREE	STATION ALL IN ONE 32" FULL HD VM 4K HDMI IN WALL VERSION
	STATION AIO 55	VID-STA-55E01-0001	STATION ALL IN ONE 55" 4K VM 4K SDI VERSION ENCASTREE	STATION ALL IN ONE 55" 4K VM 4K SDI IN WALL VERSION
		VID-STA-55E02-0001	STATION ALL IN ONE 55" 4K VM 4K HDMI VERSION ENCASTREE	STATION ALL IN ONE 55" 4K VM 4K HDMI IN WALL VERSION
STATION MONITEUR				
Modèle / Model	Type	Référence / Reference	Désignation française	English designation
STATION MONITEUR	STATION MONITEUR 55	VID-STA-55E00-0001	STATION MONITEUR 55" 4K VERSION ENCASTREE	STATION MONITOR 55" 4K IN WALL VERSION
STATION DICOM VIEWER				
Modèle / Model	Type	Référence / Reference	Désignation française	English designation
STATION DV	STATION DV 55	VID-STA-55S00-0002	STATION DICOM VIEWER 55" 4K FIXATION EN SAILLIE, ENTREES LATERALES 2xHDMI, RACCORDEMENT RESEAU ENCASTRE	STATION DICOM VIEWER 55" 4K FLUSH-MOUNTED VERSION, SIDE CONNECTIONS 2xHDMI, FLUSH NETWORK CONNECTION
		VID-STA-55S00-0006	STATION DICOM VIEWER 55" 4K FIXATION EN SAILLIE, ENTREES LATERALES 1xHDMI, RACCORDEMENT RESEAU ENCASTRE + RESERVATION ENTREE 1xHDMI	STATION DICOM VIEWER 55" 4K FLUSH-MOUNTED VERSION, SIDE CONNECTIONS 1xHDMI, FLUSH NETWORK CONNECTION + INPUT PROVISION 1xHDMI
		VID-STA-55S00-0011	STATION DICOM VIEWER 55" 4K FIXATION EN SAILLIE, RACCORDEMENT RESEAU ENCASTRE + RESERVATION ENTREE 2xHDMI	STATION DICOM VIEWER 55" 4K FLUSH-MOUNTED VERSION, FLUSH NETWORK CONNECTION + INPUT PROVISION 2xHDMI
STATION PSC (PACS STREAMING CAPTURE)				
Modèle / Model	Type	Référence / Reference	Désignation française	English designation
STATION PSC	STATION PSC 55	VID-STA-55S00-2001	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP INTEGRES, ENTREES LATERALES 2xHDMI, RACCORDEMENT ENCASTRE	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH BUILT-IN SPEAKER, 2xHDMI SIDE INLETS, RECESSED CONNECTION
		VID-STA-55S00-2002	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP INTEGRES, ENTREES LATERALES 1xHDMI, RACCORDEMENT ENCASTRE + RESERVATION ENTREE 1xHDMI	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH BUILT-IN SPEAKER, 1xHDMI SIDE INLET, RECESSED CONNECTION + 1xHDMI REAR INPUT RESERVATION
		VID-STA-55S00-2003	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP INTEGRES, RACCORDEMENT RESEAU ENCASTRE + RESERVATION ENTREE 2xHDMI	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH BUILT-IN SPEAKER, REAR RECESSED NETWORK CONNECTION + 2xHDMI REAR INPUTS RESERVATION
		VID-STA-55S00-2005	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP PLAFONNIER, ENTREES LATERALES 2xHDMI, RACCORDEMENT ENCASTRE	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH CEILING SPEAKER, 2xHDMI SIDE INLETS, RECESSED CONNECTION
		VID-STA-55S00-2006	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP PLAFONNIER, ENTREES LATERALES 1xHDMI, RACCORDEMENT ENCASTRE + RESERVATION ENTREE 1xHDMI	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH CEILING SPEAKER, 1xHDMI SIDE INLET, RECESSED CONNECTION + 1xHDMI REAR INPUT RESERVATION
		VID-STA-55S00-2007	STATION PSC 55" 4K TACTILE, FIXATION EN SAILLIE, AVEC HP PLAFONNIER, RACCORDEMENT RESEAU ENCASTRE + RESERVATION ENTREE 2xHDMI	PSC 55" 4K TOUCH, WALL MOUNT STATION, WITH CEILING SPEAKER, REAR RECESSED NETWORK CONNECTION + 2xHDMI REAR INPUTS RESERVATION
STATION CONTROL				
Modèle / Model	Type	Référence / Reference	Désignation française	English designation
STATION CONTROL	STATION CONTROL 22	VID-STA-22SPP-0001	STATION MULTIMEDIA SMS 22 AVEC CAPTURE 2 CANAUX	SMS 22 MULTIMEDIA STATION WITH 2 CHANNEL CAPTURE
		VID-STA-22DEMO-0001	STATION DE DEMO 22" ECRAN AVEC CAPTURE	DEMO 22 MULTIMEDIA STATION WITH CAPTURE

STATION SMART				
Modele / Model	Type	Reference / Reference	Designation française	English designation
STATION SMART	STATION SMART 32	VID-STA-32S02-0001	STATION SMART 32" ECRAN TACTILE FULL-HD, HP INTEGRE , VIDEO 4K HDMI ET AUDIO, ENTRÉES FRONTALES 1xUSB + 1xXLR + 1xBLUETOOTH + 2xHDMI + 1 CONFIGURABLE EN HDMI OU 12GSDI	SMART 32" FULL-HD TOUCH SCREEN, BUILT-IN SPEAKER, HDMI 4K VIDEO AND AUDIO, FRONT INPUT 1xUSB + 1xXLR + 1xBLUETOOTH + 2xHDMI + 1 CONFIGURABLE EN HDMI OR 12GSDI
	STATION SMART 32	VID-STA-32S02-0002	STATION SMART 32" ECRAN TACTILE FULL-HD, VIDEO 4K HDMI ET AUDIO ENTRÉES FRONTALES 1xUSB + 1 XLR + 1 BLUETOOTH + 2xHDMI + 1 CONFIGURABLE EN HDMI OU 12GSDI	SMART 32" FULL-HD TOUCH SCREEN, CEILING SPEAKER, HDMI 4K VIDEO AND AUDIO, FRONT INPUT 1xUSB + 1xXLR + 1xBLUETOOTH + 2xHDMI + 1 CO NFIGURABLE HDMI OR 12GSDI
	STATION SMART 32	VID-STA-32S01-0001	STATION SMART 32" ECRAN TACTILE FULL-HD, VIDEO 4K 12G-SDI ET AUDIO ENTRÉES FRONTALES 1xUSB + 1 XLR + 1 BLUETOOTH + 2x12G-SDI + 1 CONFIGURABLE EN 12GSDI OU HDMI	SMART 32" FULL-HD TOUCH SCREEN, BUILT-IN SPEAKER, 12G-SDI 4K VIDEO AND AUDIO, FRONT INPUT 1xUSB + 1xXLR + 1xBLUETOOTH + 2xHDMI + 1 CONFIGURABLE 12GSDI OR HDMI
	STATION SMART 32	VID-STA-32S01-0002	STATION SMART 32" ECRAN TACTILE FULL-HD, VIDEO 4K 12G-SDI ET AUDIO ENTRÉES FRONTALES 1xUSB + 1 XLR + 1 BLUETOOTH + 2x12G-SDI + 1 CONFIGURABLE EN 12GSDI OU HDMI	SMART 32" FULL-HD TOUCH SCREEN, CEILING SPEAKER, 12G-SDI 4K VIDEO AND AUDIO, FRONT INPUT 1xUSB + 1xXLR + 1xBLUETOOTH + 2xHDMI + 1 CONFIGURABLE 12GSDI OR HDMI
STATION DEMO				
Modele / Model	Type	Reference / Reference	Designation française	English designation
STATION DEMO	STATION DEMO	VID-STA-22DEMO-0001	STATION DE DEMO 22" ECRAN TACTILE FULL-HD, VIDEO 4K HDMI ET AUDIO, ENTRÉES COTÉ INFÉRIEUR USB + BLUETOOTH + HDMI STATION AVEC SON PIED ET ACCESSOIRES DANS VALISE DE TRANSPORT À ROULETTES FOURNI AVEC CORDON SECTEUR NF/SCHUKO	22" FULL-HD TOUCHSCREEN DEMO STATION, 4K HDMI VIDEO AND AUDIO INPUTS LOWER SIDE USB + BLUETOOTH + HDMI STATION WITH STAND AND ACCESSORIES IN ROLLING CARRYING CASE WITH POWER CORD NF/SCHUKO
ACCESSOIRES / ACCESSORIES				
Référence	Designation française		English designation	
VID-ACS-03-00-0001	ENSEMBLE DE BASE AUDIO POUR STATION ALL IN ONE		AUDIO BASE SET FOR STATION ALL IN ONE	
VID-ACS-03-00-0002	SET DE 2 HAUT PARLEURS PLAFONNIERS + CABLE HP 2X15M		SET OF 2 CEILING SPEAKERS + CABLE LSP 2X15M	
VID-ACS-03-03-0001	ENSEMBLE MICRO OREILLETTE BLUETOOTH		BLUETOOTH HEADSET SET	
VID-ACS-07-00-0001	CAMERA PTZ FULL HD		FULL HD PTZ IP CAMERA	
VID-ACS-08-00-0008	CLAVIER MÉDICALISÉ AZERTY POUR STATION SMS ALL IN ONE		AZERTY MEDICAL KEYBOARD FOR STATION ALL IN ONE	
VID-ACS-08-00-0009	CLAVIER MÉDICALISÉ AZERTY POUR STATION SMS ALL IN ONE		QWERTY MEDICAL KEYBOARD FOR STATION ALL IN ONE	
VID-ACS-08-00-0010	CLAVIER MÉDICALISÉ AZERTY		AZERTY MEDICAL KEYBOARD	
VID-ACS-08-00-0011	CLAVIER MÉDICALISÉ QWERTY		QWERTY MEDICAL KEYBOARD	
VID-ACS-08-00-0012	CLAVIER MÉDICALISÉ AZERTY (FR) BASCULANT POUR STATION SMART 32		AZERTY MEDICAL KEYBOARD FOR STATION SMART 32	
VID-ACS-08-00-0013	CLAVIER MÉDICALISÉ QWERTY (EN) BASCULANT POUR STATION SMART 32		QWERTY MEDICAL KEYBOARD FOR STATION SMART 32	
VID-ACS-08-00-0003	SCANNER, DOUCHETTE FILAIRE		WIRED SCANNER	
VID-ACS-08-00-0004	SCANNER, DOUCHETTE SANS FILS		WIRELESS SCANNER	
VID-ACS-08-00-0001	MÉMOIRE SUPPLÉMENTAIRE POUR DISQUE DUR HDD 1TB		ADDITIONAL MEMORY FOR 1TB HDD HARD DRIVE	
VID-ACS-08-04-0001	PÉDALE DOUBLE FILAIRE AVEC CABLE XLR 5M		DOUBLE WIRED PEDAL WITH XLR CABLE 5M	
VID-ACS-09-00-0002	JEU DE 4 AIMANTS POUR FILM RADIOLOGIQUE		SET OF 4 MAGNETS FOR X-RAY FILM	
VID-CON-01-02-0001	ADAPTATION POUR ENTRÉE EXTERNE SDI (POUR ROUTAGE 18G-HDMI)		SIGNAL ADAPTATION FOR SDI EXTERNAL INPUT (FOR 18G-HDMI ROUTING)	
VID-CON-06-02-0001	ADAPTATEUR DVI-D FEMELLE /HDMI MALE		DVI-D FEMALE /HDMI MALE ADAPTER	
VID-ACS-03-07-0003	RETOUR AUDIO BI-DIRECTIONNEL SOUS IP(STREAMING TALK BACK) POUR STATION ALL IN ONE		BI-DIRECTIONAL AUDIO FEEDBACK UNDER IP (STREAMING TALK BACK) FOR STATION ALL IN ONE	
VID-ACS-03-00-0001	ENSEMBLE DE BASE AUDIO POUR STATION ALL IN ONE		AUDIO BASE SET FOR STATION ALL IN ONE	
INTV-SYS-RAC-009	COFFRET 19P 6U NOIR MURAL PROF 450MM		RACK 19P 6U BLACK WALL MOUNT PROF 450MM	
INTV-SYS-RAC-002	PANNEAU 19P 16 8 PRISES 2P+T		PANEL 19P 16 8 SOCKETS 2P+T	
INTV-SYS-RAC-003	ETAGERE FIXE NOIRE 19P 1U PERFOREE PROF 440MM		FIXED BLACK SHELF 19P 1U PIERCED PROF 440MM	
INTV-SYS-RAC-005	ETAGERE FIXE PERFOREE GRISE 19" 1U CHARGE 10KGS PROF 255MM		FIXED SHELF GREY 19" 1U PAYLOAD 10KG DEPTH 255MM	
INTV-SYS-MPC-003	SUPPORT MURAL POUR PANEL PC VESA 75 / 100 / 200 INCLINABLE ORIENTABLE		WALL STAND FOR PANEL PC VESA 75 / 100 / 200 TILTABLE ORIENTABLE	
VID-ACS-03-03-0001	ENSEMBLE MICRO OREILLETTE BLUETOOTH		BLUETOOTH HEADSET SET	
VID-EXT-00I01-0001	ENTRÉE SDI SUR BRAS POUR STATION ALL IN ONE		SDI INPUT ON PENDANT FOR ALL IN ONE STATION	
VID-CAB-20M01-0001	CABLE LIAISON 20M SDI		SDI 20M CONNECTION CABLE	
VID-EXT-00I02-0001	ENTRÉE HDMI SUR BRAS POUR STATION ALL IN ONE		HDMI INPUT ON PENDANT FOR ALL IN ONE STATION	
VID-FIB-20M02-0001	CABLE DE LIAISON 20M HDMI FIBRE OPTIQUE		HDMI 20M OPTICAL FIBER	

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ANNEXE IV DU REGLEMENT 2017/745

EU DECLARATION OF CONFORMITY
ANNEX IV OF REGULATION 2017/745

Ces dispositifs médicaux sont conformes aux exigences du règlement 2017/745 relatif aux dispositifs médicaux, ainsi qu'aux principales normes relatives à ces dispositifs (NF EN 60601-1, NF EN 60601-1-2). Ils sont également conformes à toute autre norme technique et de sécurité applicable. La suite logicielle SMS installée dans les stations AIO répond aux exigences de la norme IEC 82304-1 (des produits logiciels de santé).

Ces dispositifs médicaux appartiennent à la classe I selon l'annexe VIII du règlement 2017/745.

D'autre part, ces dispositifs médicaux sont également conformes à la directive 2011/65/UE relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, et ces adaptations successives.

Je m'engage à appliquer et faire appliquer toutes les évolutions des réglementations ainsi que des normes applicables sur ces dispositifs.

FAIT A CROIX, LE 14/04/2025

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 (NF EN 60601-1, NF EN 60601-1-2). They also comply with any other current technical and safety standards. The SMS software suite installed in stations meets the requirements of the IEC 82304-1 standard (for health software products).

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

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 14/04/2025

DENIS PAPIN
DIRECTEUR GENERAL / GENERAL MANAGER

