

Declaration

According to Medical Device Directive 93/42/EEC, Article 12

The company

STORZ MEDICAL AG
Lohstampfstrasse 8
CH – 8274 Tägerwilen

hereby declares, that for our medical device product

MODULITH® SLK with product code **0L**

and marketing system-affix

“intelekt”

in combination with below mentioned products,

- a) an internal control and inspection method is used to verify the mutual compatibility of the below mentioned products according to the manufacturers' instructions,
- b) all operations are carried out in accordance with these instructions,
- c) the system is packed and all relevant information to users incorporating relevant instructions from the manufacturers is supplied.

The conformity assessment of the listed products is done by the respective manufacturer.

Tägerwilen, October 21st, 2020



Jörg Freidinger
Director Quality Management & Regulatory Affairs



X-Ray

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
X-Ray C-Arc	TCA 6R	27981	TECHNIX S.p.A	COC_ZL_023_01_00
X-Ray C-Arc	Compact (230V/ 115V)	20114/ 22548	Ziehm Imaging GmbH	COC_ZL_022_01_02
X-Ray C-Arc	TCA 6S (230V/115V)	19768/ 22546	TECHNIX S.p.A.	COC_ZL_023_01_00
X-Ray C-Arc	TCA 6 EYES	31996	TECHNIX S.p.A.	COC_ZL_023_01_00
X-Ray C-Arc	Ziehm 8000	27683	Ziehm Imaging GmbH	COC_ZL_022_01_02
X-Ray C-Arc	Ziehm Solo	20229	Ziehm Imaging GmbH	COC_ZL_022_01_02
X-Ray C-Arc	Cios Connect	10308193	Siemens AG, Germany	COC_ZL_033_01_02
X-Ray C-Arc	Cios Fusion	10308192	Siemens AG, Germany	COC_ZL_034_01_02
X-Ray C-Arc	Cios Select	10893686	Siemens Shanghai Medical Equipment Ltd.	COC_ZL_035_01_02
X-Ray C-Arc	Cios Fit	11250738	Siemens Healthcare Pvt. Ltd India	COC_PM_ECR_8091_01_02
X-Ray C-Arc	Arco FP	28739	ATS s.r.l.	COC_ZL_017_01_00
X-Ray C-arc	Arco FP-s	31951	ATS s.r.l.	COC_PM_ECR_8249_02_02 COC_PM_ECR_8249_01_02

Patient table

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
Patient table	TLX	27966	TECHNIX S.p.A	COC_ZL_023_01_00
Patient table	CFLU 401 Lithotripsy/ Urology table	27977	Oakworks, Inc®	COC_ZL_029_01_02

Urological work Station

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
Fluroscopy system for urological diagnostics (GMDN: 37633)	Uroskop Omnia Max	10762473	Siemens Healthcare GmbH X-Ray products (XP)	COC_PM_ECR_7721_01_02

Ultrasound

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
Ultrasound	F37 (230V/ 115V)	26839 (230V) 26840 (115V)	Hitachi Ltd	COC_ZL_021_01_02
Ultrasound	Prosound 6 (230V/ 115V)	21723 (230V) 21724 (115V)	Hitachi Ltd	COC_ZL_021_01_02

Ultrasound	Prosound 2 (230V/ 115V)	21721 (230V) 21722 (115V)	Hitachi Ltd	COC_ZL_021_01_02
Ultrasound	HS50	28926	Samsung	028238_01_PM33_01_02
Ultrasound	HS30	31795	Samsung	COC_PM_ECR_7447_01_02

ECG

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
ECG Product for triggered shock wave release	StorM-Sync S	21731	STORZ MEDICAL AG	COC_GF_016_01_00
Patient Monitor	iPM 8	24392	Shenzhen Mindray Biomedical Electronics Co., Ltd.	COC_ZL_019_01_02
Patient Monitor	ePM10	31546	Shenzhen Mindray Biomedical Electronics Co., Ltd.	COC_ZL_019_02_02

Thermal Printer for X-ray and Ultrasound

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
Video Printer	UP898MD	25932/ 28922/ 28925	Sony Corporation Japan	COC_ZL_020_01_02

Uro-Accessories

Product	Model	REF	Manufacturer	Conformity 93/42/EEC
Uro Kit	Technix TLX	27974	TECHNIX S.p.A	COC_ZL_023_01_00
Leg holder	F-KCP	27783	Allen Amatech	COC_ZL_018_04_02 COC_ZL_018_05_02
Drain Bag	F-UC32	21586	Allen Amatech	COC_ZL_041_01_02