

SAO Y BẢN CHÍNH  
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# EC Declaration of Conformity



KS. Nguyễn Văn Lịch

For the following products:

**SURGICAL TABLE Accessories**

( Product Name )

**Universal Surgical Table Accessories Listed in Annex**

( Model Designation )

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of Member States concerning Medical Device Directive 93/42/EEC as amended by 2007/47/EC with the compliance of conformity assessment Annex VII to be self-declaration.

For the evaluation regarding the **Class** I/IIa/IIb/III product safety aspects, the following **harmonized standards** are applied:

All surgical table accessories : EN ISO 14971(:2012); EN1041(:2008); EN 62366(:2008); EN980(:2008)

The following European Authorized Representative is stated to the declaration:

**BenQ Europe B.V.**

( Company Name )

**Meerenakkerweg 1, 5652AR, Eindhoven, Netherlands**

( Company Address )

The following person is responsible for the compliance of declaration:

**BenQ Medical Technology Corporation**

( Manufacturer Name )

**Head Office : 7<sup>th</sup> Floor, No.46, Zhou-z Street, Nei-hu, Taipei 114, Taiwan, R.O.C.  
Gueishan Factory : 3F, No. 159, Shan-Ying Road, Shan-Ding Village, Gueishan Dist., Taoyuan City 333, Taiwan, R.O.C.**

( Manufacturer Address )

**Richard Hsu / President**

4/17/2017

( Name / Position )

( Legal Signature )

( Date )



## Annex

Accessories Description	Old Part No.	New Part No.
Arm Board without Pad (BenQ Side Rail )	2101-0000-0665	2400-00002-010
Arm Board without Pad (Euro Side Rail )	2101-0000-0681	2400-00002-030
Arm Board with Pad(BenQ Side Rail ,REGULAR FABRICS)	2101-0000-0360	2400-00003-360
Arm Board with Pad(BenQ Side Rail ,SFC Cushion Mattress )	2101-0000-0357	2400-00003-380
Raised Arm Rest	2101-0000-0481	2400-00001-640
Microscopic Operating Frame for Hand	2101-0000-0109	2400-00000-610
Head, Shoulder and Arm Rest for Kidney Operation	1101-8120-0043	1900-00002-630
Wristlet (BenQ)	2101-0000-0003	2400-00000-090
Arm Restraint Cuff	2101-0000-0442	2400-00001-510
Lateral Support	2101-0000-0086	2400-00000-490
Shoulder Support	2101-0000-0087	2400-00000-500
Pad-adjustable Dorsal Operating Frame	2101-0000-0010	2400-00000-150
Lordosis Operating Frame	2101-0000-0083	2400-00000-460
Rectal Positioning Support(5600S/5800/7000)	1101-8120-0042	1900-00002-620
Rectal Positioning Support(650NS)	1101-8120-0155	1900-00003-430
Shoulder Surgery Attachment(( 650NS/7000S(N)/5600S / 5800S / 330T/Q200)	2101-0000-0290 2101-0000-0403 2101-0000-0320	2400-00001-940
Assembling Dorsal Operating Pad Set	2101-0000-0307	2400-00001-100
Pubis-sacrum-sternum Support	2101-0000-0371	2400-00001-321
Back-buttocks Support	2101-0000-0372	2400-00001-331
Shoulder Extension Plate (for 5600/5800/7000 series)	2101-0000-0440	2400-00001-500
Table Width Extension Plate(BenQ)	2101-0000-0517	2400-00001-750
Table Width Extension Plate(Euro)	2101-0000-0518	2400-00001-760
Leg Crutches	2101-0000-0470	2400-00001-600
Lithotomy Holder	2101-0000-0116 *2	2400-00000-660
Foot Rest with mattress ( R )	2101-0000-0089	2400-00000-510
Foot Rest with mattress ( L )	2101-0000-0093	2400-00000-540
Knee Rrest (330/5600S/7000/Q100)	2101-0000-0148	2400-00000-780
Knee Rrest (650NS)	2101-0000-0404	2400-00001-400
Urology Drain Tray Set(For 330T/330TK)	2100-0000-0004	2400-00000-020
Urology Drain Tray Set (For 330TF/330TKF)	2101-0000-0004	2400-00000-100
Urology Drain Tray Set (For 7000N)	2101-0000-0005	2400-00000-110
Urology Drain Tray Set (For 5600S/5600SF07/7000S)	2101-0000-0006	2400-00000-120
Urology Drain Tray Set (For 650NS only)	2101-0000-0405	2400-00001-410
Contamination Bucket	2101-0000-0115	2400-00000-650
X-ray Top (For 330T)	2101-0000-0036	2400-00000-060



