



EC Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Manufacturer

Name: TNQ CO., LTD.

Address: 301, B Building, No.2-1, NanLi Road, JiangNan Village, NanCun Town, PanYu District, Guangzhou City, Guangdong P.R., China

EC Representative

Name: **SUNGO Europe B.V.** VAT NL857821659B01

Address: **Olympisch Stadion 24, 1076DE Amsterdam**

Contact : SUNGO Secretary

Tel/Fax: +31 (0) 2021 11106

E-mail: ec.rep@sungogroup.com

Product

Name: Velcro Tourniquet, Buckle Tourniquet, Disposable Tourniquet, Arm Sling, Simply Arm Sling, Disposable Arm sling, Injection practice pad, Restraint Belt, Cervical Collar, Gait/Transfer Belt, Elastic Bandage, Sports Tape Series(Trainer's Tape, Porous Sport Tape, ElastoTape, LightRip, LeukoTapes), Dressing Tray, Identification Tape, Doctor Coat, Urine Cup, Medical Hand Brush, Disposable Silicone Medical Brush

Type See [ATTACHMENT](#) of details

Classification I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

Standard(s): EN ISO 14971:2012, EN ISO 15223-1: 2016, EN 1041: 2008, EN ISO 10993-1:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010

Related to Directive(s): Medical Device Directive(93/42/EEC) Including Directive 2007/47/EC

Signature :

For and on behalf of
TNQ CO., LIMITED
特樂擴醫療器械有限公司

Authorized Signature(s)

Date 2018-11-16

ATTACHMENT

Product	Model
Velcro tourniquet	TNQ-T0E00,TNQ-T0E01,TNQ-T0E02,TNQ-T0E03, TNQ-T0F00
Buckle tourniquet	TNQ-T0A00,TNQ-T0B00,TNQ-T0C00,TNQ-T0D00, TNQ-T0K00, TNQ-YP00
Disposable Tourniquet	TNQ-TDT00,TNQ-TDT01,TNQ-TDT02,TNQ-TDT03
Arm Sling	TNQ-A0A00,TNQ-A0C00; S,M,L,XL
Simply Arm Sling	TNQ-A0D00
Disposable Arm sling	TNQ-A0E00; S,M,L,XL
Injection practice pad	TNQ-I0A00,TNQ-I0A01,TNQ-I0A02; Belt part: without belt,30cm,60cm,90cm; Training part:85 x75x30mm
Restraint Belt	TNQ-R0A00,TNQ-R0A00,TNQ-R0C00,TNQ-R0D00, TNQ-R0E00, TNQ-R0F00, TNQ-R0G00, TNQ-R0H00 TNQ-R0I00, TNQ-R0J00
Cervical Collar	TNQ-C0A00; S,M,L,XL
Gait/Transfer belt	TNQ-GMA00
Elastic Bandage	TNQ-H0F00
Sports Tape Series(Trainer's Tape, Porous Sport Tape, ElastoTape, LightRip, LeukoTapes)	Trainer's Tape(TNQ-H0B00); Porous Sport Tape(TNQ-H0D00); ElastoTape(TNQ-H0C00); LightRip(TNQ-H0E00); LeukoTapes(TNQH0H00)
Dressing Tray	TNQ-HYP001
Identification tape	TNQ-SBD001(Adult):245mm×25mm; TNQ-SBD002(Children):169mm×19mm; TNQ-SBD003(Mother with baby): 245x25mm,169x19mm
Doctor Coat	TNQ-DC001,TNQ-DC002; S,M,L,XL
Urine Cup	TNQ-NB001(60ML), TNQ-NB002(120ML)
Medical Hand Brush	TNQ-MHB001;8.5x5.3x3cm
Disposable Silicone medical brush	TNQ-XTG001;25x3cm
Nurse Cap	TNQ-NCX series.

Note: Special specifications according to customer requirements.

For and on behalf of
TNQ CO., LIMITED
 特樂擴醫療器械有限公司
 Authorized Signature(s)