



## Compliance Report

**Product:** Cervical Collar, Neck Traction, Neck Brace, Shoulder Brace, Elbow Brace, Wrist Brace, Knee Brace, Ankle Brace, Hinged Knee Brace, Limbs Retainer, Maternity Belt, Postpartum Belt, Lumbar Support, Foam Collar, Arm Sling, Air Cushion, Thoravest, Beactive Brace, Hallux Valgus Orthotics, Half Finger Sport Gloves, Chin Strap, Toe Separator/Bunion/Hallux Valgus, Patella Strap, Sport Bra, U Shape Pillow, Compression Running Sleeve, Waist Trainer, Ice Bag, Crutch, Air Mattress With Pump, Mesh Backrest, Glove

**Type:** See annex for details

**Product Classification:** Class I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02512

Initial Issue Date: 13 Apr 2016

*Tony Chen*

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.





## Annex to Report (No. 02512 )

Product Name	Type
Cervical Collar	AFT-1076, AFT-1078, AFT-1085
Neck Traction	AFT-1072, AFT-1073, AFT-1074, AFT-1075
Neck Brace	AFT-H001
Shoulder Brace	AFT-H002
Elbow Brace	AFT-H003
Wrist Brace	AFT-H004
Knee Brace	AFT-H005
Ankle Brace	AFT-H006
Hinged Knee Brace	AFT-1001, AFT-1002, AFT-1003
Limbs Retainer	AFT-1004
Maternity Belt	AFT-1022, AFT-1023, AFT-T001, AFT-1017, AFT-1019, AFT-1020, AFT-1014, AFT-1024
Postpartum Belt	AFT-1016, AFT-1018, AFT-1021
Lumbar Support	AFT-Y011, AFT-Y002, AFT-Y201, AFT-Y202, AFT-Y203
Foam Collar	AFT-1081
Arm Sling	AFT-A001, AFT-A002, AFT-A003
Air Cushion	AFT-1025, AFT-1026, AFT-1029
Thoravest	THO101, THO102
Beactive Brace	01135
Hallux Valgus Orthotics	AFT-BR003
Half Finger Sport Gloves	AFT-YG008

This annex is only valid if attached to the report mentioned above.





## Annex to Report (No. 02512 )

Product Name	Type
Chin Strap	AFT-E23
Toe Separator/Bunion/Hallux Valgus	AFT-B1001
Patella Strap	AFT-CH919
Sport Bra	AFT-YB007
U Shape Pillow	AFT-UP001
Compression Running Sleeve	AFT-CR001
Waist Trainer	AFT-W007
Ice Bag	AFT-I001
Crutch	AFT-W006
Air Mattress With Pump	AFT-1027,AFT-1028, AFT-1029
Mesh Backrest	AFT-001
Glove	AFT-G001

This annex is only valid if attached to the report mentioned above.