

NOVAMED®



ÇINARMED
Sağ. Hiz. San. Tic. Ltd. Şti.

EC Declaration of Conformity

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

According to the Council Directive 93/42/EEC of 14 Jun, 1993 concernig medical devices

Manufacturer :

ÇINAR MEDİKAL Sağ. Hiz. San. Tic. Ltd. Şti.
Esenkent Mah. Enbiya Sok. No:25
Tel: +90 216 573 92 26
Fax:+90 216 276 94 81

Product Group :

Medical devices and orthopedic goods

Confurmity Assesment Procedure :

Directive 93/42/EEC

Classification :

According to Council Directive Annex IX, Non invasive devices, non sterile devices and non measuring (low-risk) **Class I**

Date of first CE marking :

01.06.2013

We herewith declare that above mentioned product group meet all requirement of the council directive 93/42/EEC concerning medical devices which apply to it.

We ÇINAR MEDİKAL Sağ. Hiz. San. Tic. Ltd. Şti. Esenkent Mah. Enbiya Sok. No:25 Confirm that no decleration of conformity is neccessary for under mentioned products (as they are optional features included in the general conformity)

Product list attached (appendix list)

Murat ÇINAR
General Manager

ÇINAR MEDİKAL
SAĞLIK HİZMETLERİ SANAYİ VE TİC. LTD. ŞTİ.
Esenkent Mah. Enbiya Sok. No:25 Ümraniye/İstanbul
Tel: 444 4 904 Faks: 0216 489 40 29
Sancaktepe V.D. / 251 024 1027
Başlı No: 528927 Sermaye 250.000 TL.

NOVAMED



EC Declaration of Conformity



MEDICAL STOCKING

CODE	DESCRIPTION
NV.610	Medical Stocking Under Knee Toe open
NV.600	Medical Stocking Under Knee Toe close
NV.630	Medical Stocking AboveKnee Toe open
NV.620	Medical Stocking Above Knee Toe close
NV.650	Medical Stocking Pantyhose Toe open
NV.640	Medical Stocking Pantyhose Toe close
NV.670	Medical Stocking Under Knee Toe open
NV.660	Medical Stocking Under Knee Toe close
NV.690	Medical Stocking Above Knee Toe open
NV.680	Medical Stocking Above Knee Toe close
NV.710	Medical Stocking Pantyhose Toe open
NV.700	Medical Stocking Pantyhose Toe close
NV.720	Medical Stocking Under Knee Toe open
NV.730	Medical Stocking Above Knee Toe open
NV.740	Medical Stocking Pantyhose Toe open
NV.750	Anti Embolism Stocking Above Knee
NV.755	Anti Embolism Stocking Under Knee
NV.745	Anti Embolism Stocking Above Knee With Waist Belt
N.V.770	Travel Socks Low Pressure Under Knee Toe close
NVH.500	Pregnant Medical Stocking Pantyhose Toe close
NVL 761	Lymphedema Arm Sleeves Low Pressure Without Hand
NVL 760	Lymphedema Arm Sleeves Low Pressure With Hand
NVL 763	Lymphedema Arm Sleeves Medium Pressure Without Hand
NVL 762	Lymphedema Arm Sleeves Medium Pressure With Hand
NVL 765	Lymphedema Arm Sleeves High Pressure Without Hand
NVL 764	Lymphedema Arm Sleeves High Pressure With Hand

CERVICAL COLLAR

CODE	DESCRIPTION
120	VISCO PILLOW LARGE
120	VISCO PILLOW SMALL
1300	PHILADELPHIA CERVICAL COLLAR
1325	WIRE FRAME COLLAR
1350	PHILADELPHIA CERVICAL COLLAR TRACHEOSTOMY
1500	NELSON CERVICAL COLLAR
1700	CERVICAL CORSET WITH CHIN SUPPORT
1800	CERVICAL CORSET WITHOUT CHIN SUPPORT
2400	SPONGE CERVICAL COLLAR

NOVAMED



EC Declaration of Conformity

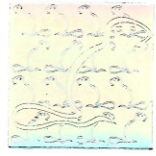
 CINARMED
 Sığ. Mlz. San. Tic. Ltd. Şti.

HAND AND ARM PRODUCTS

CODE	DESCRIPTION
150	SILICON HAND THERAPY BALL
300	CLAVICLE BANDAGE
300	CLAVICLE BANDAGE
1000	ELASTIC HAND WRIST SPLINT
1001	ELASTIC HAND WRIST SPLINT (SKIN COLOR)
1450	ARM SLING WITH ADJUSTABLE ANGLE (30)
1600	FINGER SPLINT WITH ALUMINUM BALEN
1900	HAND WRIST THUMB SPLINT WITH SUPPORT
1925	RESTING SPLINT
2800	FRONT ARM SPLINT
3000	STICK FINGER SPLINT
3025	FROG SPLINT
3050	BASEBALL SPLINT
3200	SPONGE ARM SLING WITH WAIST BELT
3250	ARM SLING WITH MESH
3800	VELPEAU BANDAGE
3800	VELPEAU BANDAGE
6000	MALLET FINGER ORTHOSIS
6700	NEOPREN TENNIS ELBOW SHORT
6710	NEOPREN TENNIS ELBOW LONG
6725	ARM ORTHOSIS WITH ADJUSTABLE ANGLE
7100	NEOPREN WRIST BRACE
7150	NEOPREN THUMB SPLINT WITH SUPPORT
7200	NEOPREN HAND WRIST SPLINT
7200	NEOPREN HAND WRIST SPLINT
7250	NEOPREN HAND WRIST SPLINT THUMB SUPPORT
7300	NEOPREN ELBOW PAD
NV-7301	KNITTED ELBOW
7800	NEOPREN SHOULDER PAD
9100	NEOPREN WRIST BRACE

WAIST CORSETS

CODE	DESCRIPTION
1100	WOOL WAIST CORSET
1160	WOOL WAIST CORSET VELCRO
2500	POSTUREX CORSET
2600	SUSPENSORY
3900	CHEST CORSET
3925	CARDIOLOGY CORSET
4100	HERNIA PAD SINGLE
4200	HERNIA PAD DOUBLE
NT-4400	NOVA WAIST PAD WITH GEL
4600	LUMBOSACRAL CORSET
4601	KNITTED LUMBOSACRAL CORSET
5400	LUMBOSTAD CORSET
5600	DORSOLUMBAR CORSET
5700	ABDOMINAL CORSET



ÇINAR MEDİKAL SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

ESENKENT MAHALLESİ ENBİYA SOKAK NO: 25 YUKARI DUDULLU
ÜMRANIYE – İSTANBUL – TURKEY

with a scope of

**MANUFACTURE OF MEDICAL STOCKINGS, CERVICAL COLLARS,
MEDICAL PRODUCTS FOR HAND AND ARM, CORSETS, MEDICAL
PRODUCTS FOR KNEE AND FOOT WITH SILICONE, ORTHOPEDIC
SHOES AND SLIPPERS**

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

"7.5.3" "7.5.4" "7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No : M 9723
Initial Certification Date : 29 January 2014
Certification Date : 26 December 2019
Expiration Date : 25 December 2022



Medical Device Q M S
TS EN ISO/IEC 17021-1
AB-0006-YS



TÜRKAK BDS NO
YS-4699-9C8F



General Manager

Kiwa Certification Services Inc.

ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey

Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74

Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.