

DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY



La sottoscritta **Calze G.T. S.r.l.**, con sede a CASALOLDO (MN), Via W. Tobagi 17/19/21, dichiara che i dispositivi medici denominati:

*We undersigned **Calze G.T. S.r.l.**, with head office addressed in CASALOLDO (MN), Via W. Tobagi 17/19/21, hereby declare that medical devices called:*

Relaxsan (Basic-Cotton-Multifiber-Microfiber)

Art. 430 Basic Pantyhose 40 den, **Art. 780** Basic Pantyhose 70 den, **Art. 760** Basic Thigh high 70 den, **Art. 750** Basic Knee high 70 den, **Art. 700** Basic Knee high No-Heel 70 den, **Art. 770** Basic Thigh high w/lace 70 den, **Art. 790** Basic Maternity Pantyhose 70 den, **Art. 880** Basic Pantyhose 140 den, **Art. 880P** Basic Pantyhose 140 den PLUS, **Art. 860** Basic Thigh high 140 den, **Art. 850** Basic Knee high 140 den, **Art. 870** Basic Thigh high w/lace 140 den, **Art. 890** Basic Maternity Pantyhose 140 den, **Art. 980** Basic Pantyhose 280 den, **Art. 960** Basic Thigh high 280 den, **Art. 950** Basic Knee high 280 den, **Art. 970** Basic Thigh high w/lace 280 den, **Art. 740** Cotton Pantyhose 70 den, **Art. 840** Cotton Pantyhose 140 den, **Art. 850C** Cotton Knee High 140 den, **Art. 870C** Cotton Thigh high w/lace 140 den, **Art. 940** Cotton Pantyhose 280 den, **Art. 750M** Microfiber Knee high 70 den, **Art. 780M** Microfiber Pantyhose 70 den, **Art. 770M** Microfiber Thigh high w/lace 70 den, **Art. 790M** Microfiber Maternity Pantyhose 70 den, **Art. 850M** Microfiber Knee high 140 den, **Art. 880M** Microfiber Pantyhose 140 den, **Art. 870M** Microfiber Thigh high w/lace 140 den, **Art. 890M** Microfiber Maternity Pantyhose 140 den, **Art. 480F** Multifiber Pantyhose 40 den, **Art. 450F** Multifiber Knee high 40 den, **Art. 780F** Multifiber Pantyhose 70 den, **Art. 750F** Multifiber Knee high 70 den, **Art. 770F** Multifiber Thigh high w/lace 70 den, **Art. 880F** Multifiber Pantyhose 140 den, **Art. 850F** Multifiber Knee high 140 den, **Art. 870F** Multifiber Thigh high w/lace 140 den,

Relaxsan Cotton Socks

Art. 820 Cotton Socks 18-22 mmHg, **Art. 830** Cotton Socks 18-22 mmHg X-Static, **Art. 920** Cotton Socks 22-27 mmHg

Relaxsan Diabetic and sensitive feet socks and TOE socks

Art. 550 Diabetic Socks X-Static, **Art. 550L** Diabetic Socks Long X-Static, **Art. 560** Diabetic Socks Crabion, **Art. 560L** Diabetic Socks Long Crabion, **Art. 650C** Cotton Diabetic TOE Socks.

Relaxsan RelaxMaternity

Art. 5100 RelaxMaternity PRE, **Art. 5200** RelaxMaternity SLIM, **Art. 5300** RelaxMaternity SUPPORT, **Art. 5150** RelaxMaternity PRE SILVER, **Art. 5400** RelaxMaternity SILVER BELT, **Art. 5700** RelaxMaternity NURSING BRA

FarmaCell

Art. 102 Minishort Classic FarmaCell Basic, **Art. 112** Short Classic FarmaCell Basic, **Art. 113** Short Top FarmaCell Basic, **Art. 122** Fitness Classic FarmaCell Basic, **Art. 123** Fitness Top FarmaCell Basic, **Art. 132** Fuseaux Classic FarmaCell Basic, **Art. 133** Fuseaux Extra FarmaCell Basic, **Art. 142** Vest Classic FarmaCell Basic, **Art. 143** Vest Long Sleeve FarmaCell Basic, **Art. 302** Minishort Classic FarmaCell Shape, **Art. 312** Short Classic FarmaCell Shape, **Art. 342** Vest Classic FarmaCell Shape, **Art. 512** Short Classic FarmaCell Silver, **Art. 522** Fitness Classic FarmaCell Silver, **Art. 412** Short Classic FarmaCell Milk, **Art. 413** Short Top FarmaCell Milk.

Relaxsan Medicale

Art. M0350A Anti-Embolism AD Knee High, **Art. M0370A** Anti-Embolism AGH Thigh high w/lace, **Art. M0380LA** Anti-Embolism AGTL Left Mono Pantyhose, **Art. M0380RA** Anti-Embolism AGTR Right Mono Pantyhose, **Art. M1350A** Anti-Embolism AD Knee High, **Art. M1370A** Anti-Embolism AGH Thigh high w/lace, **Art. M1380LA** Anti-Embolism AGTL Left Mono Pantyhose, **Art. M1380RA** Anti-Embolism AGTR Right Mono Pantyhose, **Art. M1450** Classic AD Knee High Class I, **Art. M1460** Classic AG Thigh High Class I, **Art. M1470** Classic AGH Thigh high w/lace Class I, **Art. M1480L** Classic AGTL Left Mono Pantyhose Class I, **Art. M1480R** Classic AGTR Right Mono Pantyhose Class I, **Art. M1480** Classic AT Pantyhose Class I, **Art. M1490** Classic ATM Maternity Pantyhose Class I, **Art. M1150** Soft AD Knee High Class I, **Art. M1170** Soft AGH Thigh high w/lace Class I, **Art. M1180** Soft AT Pantyhose Class I, **Art. M1190** Soft ATM Maternity Pantyhose Class I, **Art. M1050** Cotton AD Knee High Class I, **Art. M1070** Cotton AGH Thigh high w/lace Class I, **Art. M1080** Cotton AT Pantyhose Class I, **Art. M1090** Cotton ATM Maternity Pantyhose Class I,

Art. M2450 Classic AD Knee High Class II, **Art. M2460** Classic AG Thigh High Class II, **Art. M2470** Classic AGH Thigh high w/lace Class II, **Art. M2480L** Classic AGTL Left Mono Pantyhose Class II, **Art. M2480R** Classic AGTR Right Mono Pantyhose Class II, **Art. M2480** Classic AT Pantyhose Class II, **Art. M2490** Classic ATM Maternity Pantyhose Class II, **Art. M2150** Soft AD Knee High Class II, **Art. M2170** Soft AGH Thigh high w/lace Class II, **Art. M2180** Soft AT Pantyhose Class II, **Art. M2190** Soft ATM Maternity Pantyhose Class II, **Art. M2050** Cotton AD Knee High Class II, **Art. M2070** Cotton AGH Thigh high w/lace Class II, **Art. M2080** Cotton AT Pantyhose Class II, **Art. M2090** Cotton ATM Maternity Pantyhose Class II, **Art. M2250** Silver AD Knee High Class II, **Art. M3450** Classic AD Knee High Class III, **Art. M3460** Classic AG Thigh High Class III, **Art. M3470** Classic AGH Thigh high w/lace Class III, **Art. M3480** Classic AT Pantyhose Class III,

RelaxSan Ortopedica

Art. 1200 Men's half sleeve elasticised undershirt with knitted-in band, **Art. 1200D** Men's half sleeve elasticised, double-back undershirt with knitted-in band, **Art. 1300** Men's wide shoulder elasticised vest with knitted-in band, **Art. 1400** Men's long sleeve elasticised undershirt with knitted-in band, **Art. 1500** Men's wide shoulder elasticised cotton vest with knitted-in band, **Art. 4000** Men's tight, **Art. 2200** Women's half sleeve elasticized undershirt with knitted-in band, **Art. 2200D** Women's half sleeve elasticized, double-back undershirt with knitted-in band, **Art. 2300** Women's wide shoulder elasticized camisole with knitted-in band, **Art. 2400** Women's long sleeve elasticized undershirt with knitted-in band, **Art. 2500** Women's thin shoulder elasticized camisole with knitted-in band, **Art. 4050** Women's tights, **Art. 40100** Orthopaedic wristband, beige, **Art. 40150** Orthopaedic wristband, white, **Art. 40200** Orthopaedic mitten, **Art. M1800** Mitten/wristband with support aluminium insert, **Art. M1900** Mitten/wristband with support aluminium insert and Velcro fastener, **Art. 50100** KL.2 compression poliextensive tubular ankle band, **Art. 50200** KL.2 compression poliextensive tubular knee-band, **Art. 50300** KL.2 compression poliextensive tubular calf band, **Art. C4400** Elastic ankle band, **Art. 70100** Microfiber KL.1 compression monoextensive knee-high socks, **Art. 70200** KL.1 compression monoextensive knee-band, **Art. 70300** KL.1 compression monoextensive ankle band, **Art. 70400** KL.1 compression monoextensive calf band, **Art. 70500** KL.1 compression monoextensive thigh band, **Art. CA4200** Thorax band, **Art. CEU20** Light truss, h 14 cm, **Art. FPV28** Poliextensive postoperative cotton band with Velcro fastener, height 28 cm, UNISEX model, **Art. FPV28D** Poliextensive postoperative band with easy to shape cotton stiffeners and Velcro fastener, height 28 cm. Women's model, **Art. COR1600** Flexible vertebral support, **Art. COR3200** Lumbar band, **Art. COR3300** Vertebral and lumbar support, **Art. COR2026** Light orthopaedic corset with 4 stiffeners and Velcro fastener, **Art. COR20266** Orthopaedic corset with Velcro fastener, **Art. SPORFLEX** Polyvalent girdle with Velcro fastener, **Art. LCG01** Tubular thermal knee-band, beige, **Art. LGB01** Tubular thermal knee-band, white, **Art. LG02** Tubular thermal elbow-band, **Art. LS07** Anatomic shoulder cover made from wool, **Art. LCF221** Tubular thermal belt made from wool and cotton, h. 22 cm, **Art. LCF271** Tubular thermal belt made from wool and cotton, h. 27 cm, **Art. LCF311** Tubular thermal belt made from wool and cotton, h. 31 cm, **Art. LF281** Thermal belt made from poliextensive wool, h 28 cm, **Art. B3000** Arm/Shoulder support, **Art. G2700** Knee-band with stiffeners, **Art. G2800** Knee-band with stiffeners and Velcro fastener, **Art. COL100** Soft sponge-cloth collar, **Art. COL200** Stiff plastic collar.

classe di rischio I, in accordo alla regola 1 dell'Allegato IX della Direttiva 93/42/CEE, (recepita in Italia con Decreto Legislativo 24 febbraio 1997, n. 46, e successive modificazioni),

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE come riportato nei rispettivi Fascicoli Tecnici a disposizione presso l'Azienda;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata Direttiva.

risk class I, according to Directive 93/42/EEC, rule 1, Annex IX (enforced in Italy by Legislative Decree n. 46 dated 24/02/1997 and further amendments),

- comply with essential requirements and dispositions of Directive 93/42/EEC, as per relevant Technical Files kept on the premises of the Company;
- are manufactured according to the Quality System which satisfies requirements of Annex VII of the above mentioned directive.

Casaloldo, 04/01/2010