

DECLARATION OF CONFORMITY



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. 780A** Basic Pantyhose 70 den Open Toe, **Art. 760** Basic Thigh high 70 den, **Art. 750** Basic Knee high 70 den, **Art. 750A** Basic Knee high 70 den Open Toe, **Art. 700** Basic Knee high No-Heel 70 den, **Art. 770** Basic Thigh high w/lace 70 den, **Art. 770A** Basic Thigh high w/lace 70 den Open Toe, **Art. 790** Basic Maternity Pantyhose 70 den, **Art. 880** Basic Pantyhose 140 den, **Art. 880A** Basic Pantyhose 140 den Open Toe, **Art. 880P** Basic Pantyhose 140 den PLUS, **Art. 860** Basic Thigh high 140 den, **Art. 850** Basic Knee high 140 den, **Art. 850A** Basic Knee high 140 den Open Toe, **Art. 850P** Basic Knee high 140 den PLUS, **Art. 870** Basic Thigh high w/lace 140 den, **Art. 870A** Basic Thigh high w/lace 140 den Open Toe, **Art. 870P** Basic Thigh high w/lace 140 den PLUS, **Art. 890** Basic Maternity Pantyhose 140 den, **Art. 980** Basic Pantyhose 280 den, **Art. 980A** Basic Pantyhose 280 den Open Toe, **Art. 960** Basic Thigh high 280 den, **Art. 960A** Basic Thigh high 280 den Open Toe, **Art. 950** Basic Knee high 280 den, **Art. 950A** Basic Knee high 280 den Open Toe, **Art. 970** Basic Thigh high w/lace 280 den, **Art. 970A** Basic Thigh high w/lace 280 den Open Toe, **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** Prestige Multifiber Pantyhose 70 den, **Art. 750F** Prestige Multifiber Knee high 70 den, **Art. 770F** Prestige Multifiber Thigh high w/lace 70 den, **Art. 880F** Prestige Multifiber Pantyhose 140 den, **Art. 850F** Prestige Multifiber Knee high 140 den, **Art. 870F** Prestige Multifiber Thigh high w/lace 140 den.

Relaxsan Compression Socks

Art. 820 Cotton Socks 18-22 mmHg, **Art. 830** Cotton Socks 18-22 mmHg X-Static, **Art. 920** Cotton Socks 22-27 mmHg, **Art. 820M** Viscose/Milk Socks 18-22 mmHg, **Art. 820B** Cotton Socks British 18-22 mmHg, **Art. 810** Fancy Cotton Socks 15-21 mmHg, **Art. 800** Sport Socks 18-22 mmHg

Relaxsan Diabetic and sensitive feet socks and TOE socks

Art. 550S Short Diabetic Socks X-Static, **Art. 550** Diabetic Socks X-Static, **Art. 550L** Diabetic Socks Long X-Static, **Art. 550P** Diabetic Socks with Soft Sole X-Static, **Art. 560S** Short Diabetic Socks Crabyon, **Art. 560** Diabetic Socks Crabyon, **Art. 560L** Diabetic Socks Long Crabyon, **Art- 650CS** Short Cotton Diabetic Toe Socks X-Static, **Art. 650C** Cotton Diabetic TOE Socks X-Static.

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. 323** Fitness Top 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. M3350A Anti-Embolism AD Knee High ECONOMY LINE 18-23 mmHg, **Art. M3370A** Anti-Embolism AGH Thigh high w/lace ECONOMY LINE 18-23 mmHg, **Art. M3380LA** Anti-Embolism AGTL Left Mono Pantyhose ECONOMY LINE 18-23 mmHg, **Art. M3380RA** Anti-Embolism AGTR Right Mono Pantyhose ECONOMY LINE 18-23 mmHg, **Art. M0350A** Anti-Embolism AD Knee High STANDARD LINE 18-23 mmHg, **Art. M0370A** Anti-Embolism AGH Thigh high w/lace STANDARD LINE 18-23 mmHg, **Art. M0380LA** Anti-Embolism AGTL Left Mono Pantyhose STANDARD LINE 18-23 mmHg, **Art. M0380RA** Anti-Embolism AGTR Right Mono Pantyhose STANDARD LINE 18-23 mmHg, **Art. M1350A** Anti-Embolism AD Knee High STANDARD LINE 25-32 mmHg, **Art. M1370A** Anti-Embolism AGH Thigh high w/lace STANDARD LINE 25-32 mmHg, **Art. M1380LA** Anti-Embolism AGTL Left Mono Pantyhose STANDARD LINE 25-32 mmHg, **Art. M1380RA** Anti-Embolism AGTR Right Mono Pantyhose STANDARD LINE 25-32 mmHg, **Art. M2350A** Anti-Embolism AD Knee High PREMIUM LINE 18-23 mmHg, **Art. M2370A** Anti-Embolism AGH Thigh high w/lace PREMIUM LINE 18-23 mmHg, **Art. M2380LA** Anti-Embolism AGTL Left Mono Pantyhose PREMIUM LINE 18-23 mmHg, **Art. M2380RA** Anti-Embolism AGTR Right Mono Pantyhose PREMIUM LINE 18-23 mmHg, **Art. M1450/M1450A** Classic AD Knee High Class I open and closed toe, **Art. M1460/M1460A** Classic AG Thigh High Class I open and closed toe, **Art. M1470/M1470A** Classic AGH Thigh high w/lace Class I open and closed toe, **Art. M1480L/M1480LA** Classic AGTL Left Mono Pantyhose Class I open and closed toe, **Art. M1480R/M1480RA** Classic AGTR Right Mono Pantyhose Class I open and closed toe, **Art. M1480/M1480A** Classic AT Pantyhose Class I open and closed toe, **Art. M1480O/M1480OA** Classic AT Pantyhose Class I with front and back opening with open and closed toe, **Art. M1490/M1490A** Classic ATM Maternity Pantyhose Class I open and closed toe, **Art. M1150/M1150A** Soft AD Knee High Class I open and closed toe, **Art. M1170/M1170A** Soft AGH Thigh high w/lace Class I open and closed toe, **Art. M1180/M1180A** Soft AT Pantyhose Class I open and closed toe, **Art. M1190/M1190A** Soft ATM Maternity Pantyhose Class I open and closed toe, **Art. M1050/M1050A** Cotton AD Knee High Class I open and closed toe, **Art. M1070/M1070A** Cotton AGH Thigh high w/lace Class I open and closed toe, **Art. M1080/M1080A** Cotton AT Pantyhose Class I open and closed toe, **Art. M1090/M1090A** Cotton ATM Maternity Pantyhose Class I open and closed toe, **Art. M2450/M2450A** Classic AD Knee High Class II open and closed toe, **Art. M2460/M2460A** Classic AG Thigh High Class II open and closed toe, **Art. M2470/M2470A** Classic AGH Thigh high w/lace Class II open and closed toe, **Art. M2480L/M2480LA** Classic AGTL Left Mono Pantyhose Class II open and closed toe, **Art. M2480R/M2480RA** Classic AGTR Right Mono Pantyhose Class II open and closed toe, **Art. M2480/M2480A** Classic AT Pantyhose Class II open and closed toe, **Art. M2480O/M2480OA** Classic AT Pantyhose Class II with front and back opening with open and closed toe, **Art. M2490/M2490A** Classic ATM Maternity Pantyhose Class II open and closed toe, **Art. M2150/M2150A** Soft AD Knee High Class II open and closed toe, **Art. M2170/M2170A** Soft AGH Thigh high w/lace Class II open and closed toe, **Art. M2180/M2180A** Soft AT Pantyhose Class II open and closed toe, **Art. M2190/M2190A** Soft ATM Maternity Pantyhose Class II open and closed toe, **Art. M2050/M2050A** Cotton AD Knee High Class II open and closed toe, **Art. M2070/M2070A** Cotton AGH Thigh high w/lace Class II open and closed toe, **Art. M2080/M2080A** Cotton AT Pantyhose Class II open and closed toe, **Art. M2090/M2090A** Cotton ATM Maternity Pantyhose Class II open and closed toe, **Art. M2250A** Silver AD Knee High Class II, **Art. M3450/M3450A** Classic AD Knee High Class III open and closed toe, **Art. M3460/M3460A** Classic AG Thigh High Class III open and closed toe, **Art. M3470/M3470A** Classic AGH Thigh high w/lace Class III open and closed toe, **Art. M3480/M3480A** Classic AT Pantyhose Class III open and closed toe, **Art. M3480O/M3480OA** Classic AT Pantyhose Class III with front and back opening with open and closed toe, **Art. M1451/M1451A** Classic Cotton AD Knee High Class I open and closed toe, **Art. M1461/M1461A** Classic Cotton AG Thigh High Class I open and closed toe, **Art. M1471/M1471A** Classic Cotton AGH Thigh high w/lace Class I open and closed toe, **Art. M1481L/M1481LA** Classic Cotton AGTL Left Mono Pantyhose Class I open and closed toe, **Art. M1481R/M1481RA** Classic Cotton AGTR Right Mono Pantyhose Class I open and closed toe, **Art. M1481/M1481A** Classic Cotton AT Pantyhose Class I open and closed toe, **Art. M2451/M2451A** Classic

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Capitale Sociale € 45.900,00 i.v.

Cotton AD Knee High Class II open and closed toe, **Art. M2461/M2461A** Classic Cotton AG Thigh High Class II open and closed toe, **Art. M2471/M2471A** Classic Cotton AGH Thigh high w/lace Class II open and closed toe, **Art. M2481L/M2481LA** Classic Cotton AGTL Left Mono Pantyhose Class II open and closed toe, **Art. M2481R/M2481RA** Classic Cotton AGTR Right Mono Pantyhose Class II open and closed toe, **Art. M2481/M2481A** Classic Cotton AT Pantyhose Class II open and closed toe, **Art. M2420** Classic BH Arm Compression Sleeve Class II, **Art. M2421** Classic ZH Arm Sleeve with hand Class II, **Art. M2430** Classic BH Arm Sleeve with hooks for bra straps Class II, **Art. M2431** Classic ZH Arm Sleeve with hooks for bra straps and hand Class II, **Art. M2440** Classic BH Arm Sleeve with belt Class II, **Art. M2441** Classic ZH Arm Sleeve with belt and hand Class II,

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. 50300/50310** 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.

risk class I, according to Directive 93/42/EEC, rule 1, Annex IX (enforced in Italy by Legislative Decree No. 46/97 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy by Legislative Decree No. 37/10)

- *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, 12/01/2018

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Calze G.T. S.r.l.

Legal Representative

Corporate
brands**RELAXSAN****FarmaCell**Quality
marks**FIDUCIA
NELTESSILE**
Testato per sostanze nocive
secondo Deko-Test* Standard 100
14CX00025 CENTROCOT**ICIM**
ISO 9001
ISO 13485
Cert. n. 4434/2
Cert. n. 4435/2