

## EU DECLARATION OF CONFORMITY



**CALZE G.T. Srl**, with registered office in Via Castel Goffredo, 31/33 - 46040 Casaloldo (MN) Italy, as manufacturer of medical devices:

### Relaxsan Basic

*BASIC UDI-DI Code - 83009610001MB*  
*NSIS: 349353*

**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.

### Relaxsan Microfiber

*BASIC UDI-DI Code - 83009610003MF*  
*NSIS: 349355*

**Art. 750M** Microfiber Knee high 70 den, **Art. 780M** Microfiber Pantyhose 70 den, **Art. 780ML** Microfiber Legging 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. 880ML** Microfiber Legging 140 den, **Art. 870M** Microfiber Thigh high w/lace 140 den, **Art. 890M** Microfiber Maternity Pantyhose 140 den.

### Relaxsan Multifiber

*BASIC UDI-DI Code - 83009610004MH*  
*NSIS: 286848*

**Art. 480F** Multifiber Pantyhose 40 den, **Art. 450F** Multifiber Knee high 40 den.

**Relaxsan Prestige**

BASIC UDI-DI Code - 83009610005MK

NSIS: 349354

**Art. 780F** Prestige Pantyhose 70 den, **Art. 750F** Prestige Knee high 70 den, **Art. 770F** Prestige Thigh high w/lace 70 den, **Art. 880F** Prestige Pantyhose 140 den. **Art. 850F** Prestige Knee high 140 den, **Art. 870F** Prestige Thigh high w/lace 140 den.

**Relaxsan Compression Socks**

BASIC UDI-DI Code - 83009610006MM

NSIS: 286855 – 1993995 (Gelato Energy) – 2030520 (Essential+)

**Art. 815** Cotton Socks 18-22 mmHg Light Fiber, **Art. 820** Cotton Socks 18-22 mmHg, **Art. 830** Cotton Socks 18-22 mmHg X-Static, **Art. 920** Cotton Socks 22-27 mmHg, **Art. 930** Cotton Socks 22-27 mmHg X-Static, **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, **Art. 900** Gelato Energy 12-14 mmHg, **Art. 902** Gelato Energy 12-14 mmHg, **Art. 922** Socks Double layer 23-32 mmHg Essential+.

**Relaxsan Diabetic and sensitive feet socks and TOE socks**

BASIC UDI-DI Code - 83009610007MP

NSIS: 52778 - 52751

**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.

**Relaxsan Anti-Embolism Stockings STANDARD Line**

BASIC UDI-DI Code - 83009610008MR

NSIS: 2249015 – 2030529

**Art. M0350A** Anti-Embolism AD Knee High STANDARD LINE 18-23 mmHg, **Art. M0350AS** Anti-Embolism AD Knee High Short version STANDARD LINE 18-23 mmHg, **Art. M0350AL** Anti-Embolism AD Knee High Long version STANDARD LINE 18-23 mmHg, **Art. M0370A** Anti-Embolism AGH Thigh high w/lace STANDARD LINE 18-23 mmHg, **Art. M0370AS** Anti-Embolism AGH Thigh high w/lace Short version STANDARD LINE 18-23 mmHg, **Art. M0370AL** Anti-Embolism AGH Thigh high w/lace Long version STANDARD LINE 18-23 mmHg, **Art. M0380LA** Anti-Embolism AGTL Left Mono Pantyhose STANDARD LINE 18-23 mmHg, **Art. M0380LAS** Anti-Embolism AGTL Left Mono Pantyhose Short version STANDARD LINE 18-23 mmHg, **Art. M0380LAL** Anti-Embolism AGTL Left Mono Pantyhose Long version STANDARD LINE 18-23 mmHg, **Art. M0380RA** Anti-Embolism AGTR Right Mono Pantyhose STANDARD LINE 18-23 mmHg, **Art. M0380RAS** Anti-Embolism AGTR Right Mono Pantyhose Short version STANDARD LINE 18-23 mmHg, **Art. M0380RAL** Anti-Embolism AGTR Right Mono Pantyhose Long version STANDARD LINE 18-23 mmHg, **Art. M1350A** Anti-Embolism AD Knee High STANDARD LINE 25-32 mmHg, **Art. M1350AS** Anti-Embolism AD Knee High Short version STANDARD LINE 25-32 mmHg, **Art. M1350AL** Anti-Embolism AD Knee High Long version STANDARD LINE 25-32 mmHg, **Art. M1370A** Anti-Embolism AGH Thigh high w/lace STANDARD LINE 25-32 mmHg, **Art. M1370AS** Anti-Embolism AGH Thigh high w/lace Short version STANDARD LINE 25-32 mmHg, **Art. M1370AL** Anti-Embolism AGH Thigh high w/lace Long version STANDARD LINE 25-32 mmHg, **Art. M1380LA** Anti-Embolism AGTL Left Mono Pantyhose STANDARD LINE 25-32 mmHg, **Art. M1380LAS** Anti-Embolism AGTL Left Mono Pantyhose Short version STANDARD LINE 25-32 mmHg, **Art. M1380LAL** Anti-Embolism AGTL Left Mono Pantyhose Long version STANDARD LINE 25-32 mmHg, **Art. M1380RA** Anti-Embolism AGTR Right Mono

Pantyhose STANDARD LINE 25-32 mmHg, **Art. M1380RAS** Anti-Embolism AGTR Right Mono Pantyhose Short version STANDARD LINE 25-32 mmHg, **Art. M1380RAL** Anti-Embolism AGTR Right Mono Pantyhose Long version STANDARD LINE 25-32 mmHg, **Art. AES0110** AD below knee (open toe) STANDARD LINE 15-21 mmHg, **Art. AES0130** AGH thigh length with silicon lace top (open toe) STANDARD LINE 15-21 mmHg.

**Relaxsan Anti-Embolism Stockings PREMIUM Line**

BASIC UDI-DI Code - 83009610009MT

NSIS: 2249015 – 2030529

**Art. M2350A** Anti-Embolism AD Knee High PREMIUM LINE 18-23 mmHg, **Art. M2350AS** Anti-Embolism AD Knee High Short version PREMIUM LINE 18-23 mmHg, **Art. M2350AL** Anti-Embolism AD Knee High Long version PREMIUM LINE 18-23 mmHg, **Art. M2370A** Anti-Embolism AGH Thigh high w/lace PREMIUM LINE 18-23 mmHg, **Art. M2370AS** Anti-Embolism AGH Thigh high w/lace Short version PREMIUM LINE 18-23 mmHg, **Art. M2370AL** Anti-Embolism AGH Thigh high w/lace Long version PREMIUM LINE 18-23 mmHg, **Art. M2380LA** Anti-Embolism AGTL Left Mono Pantyhose PREMIUM LINE 18-23 mmHg, **Art. M2380LAS** Anti-Embolism AGTL Left Mono Pantyhose Short version PREMIUM LINE 18-23 mmHg, **Art. M2380LAL** Anti-Embolism AGTL Left Mono Pantyhose Long version PREMIUM LINE 18-23 mmHg, **Art. M2380RA** Anti-Embolism AGTR Right Mono Pantyhose PREMIUM LINE 18-23 mmHg, **Art. M2380RAS** Anti-Embolism AGTR Right Mono Pantyhose Short version PREMIUM LINE 18-23 mmHg, **Art. M2380RAL** Anti-Embolism AGTR Right Mono Pantyhose Long version PREMIUM LINE 18-23 mmHg, **Art. AES0110P** AD below knee (open toe) PREMIUM LINE 15-21 mmHg, **Art. AES0130P** AGH thigh length with silicon lace top (open toe) PREMIUM LINE 15-21 mmHg.

**Relaxsan Medicale Classic**

BASIC UDI-DI Code - 83009610010MC

NSIS: 2249015

**Art. M1450/M1450A** Classic AD Knee High Class I open and closed toe, **Art. M1450S/M1450AS** Classic AD Knee High Short version Class I open and closed toe, **Art. M1460/M1460A** Classic AG Thigh High Class I open and closed toe, **Art. M1460S/M1460AS** Classic AG Thigh High Short version Class I open and closed toe, **Art. M1470/M1470A** Classic AGH Thigh high w/lace Class I open and closed toe, **Art. M1470S/M1470AS** Classic AGH Thigh high w/lace Short version Class I open and closed toe, **Art. M1480L/M1480LA** Classic AGTL Left Mono Pantyhose Class I open and closed toe, **Art. M1480LS/M1480LAS** Classic AGTL Left Mono Pantyhose Short version Class I open and closed toe, **Art. M1480R/M1480RA** Classic AGTR Right Mono Pantyhose Class I open and closed toe, **Art. M1480RS/M1480RAS** Classic AGTR Right Mono Pantyhose Short version Class I open and closed toe, **Art. M1480/M1480A** Classic AT Pantyhose Class I open and closed toe, **Art. M1480S/M1480AS** Classic AT Pantyhose Short version 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. M1480OS/M1480OAS** Classic AT Pantyhose Short version 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. M1490S/M1490AS** Classic ATM Maternity Pantyhose Short version Class I open and closed toe, **Art. M2450/M2450A** Classic AD Knee High Class II open and closed toe, **Art. M2450S/M2450AS** Classic AD Knee High Short version Class II open and closed toe, **Art. M2460/M2460A** Classic AG Thigh High Class II open and closed toe, **Art. M2460S/M2460AS** Classic AG Thigh High Short version Class II open and closed toe, **Art. M2470/M2470A** Classic AGH Thigh high w/lace Class II open and closed toe, **Art. M2470S/M2470AS** Classic AGH Thigh high w/lace Short version Class II open and closed toe, **Art. M2480L/M2480LA** Classic AGTL Left Mono Pantyhose Class II open and closed toe, **Art. M2480LS/M2480LAS** Classic AGTL Left

Mono Pantyhose Short version Class II open and closed toe, **Art. M2480R/M2480RA** Classic AGTR Right Mono Pantyhose Class II open and closed toe, **Art. M2480RS/M2480RAS** Classic AGTR Right Mono Pantyhose Short version Class II open and closed toe, **Art. M2480/M2480A** Classic AT Pantyhose Class II open and closed toe, **Art. M2480S/M2480AS** Classic AT Pantyhose Short version 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. M2480OS/M2480OAS** Classic AT Pantyhose Short version 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. M2490S/M2490AS** Classic ATM Maternity Pantyhose Short version Class II open and closed toe, **Art. M3450/M3450A** Classic AD Knee High Class III open and closed toe, **Art. M3450S/M3450AS** Classic AD Knee High Short version Class III open and closed toe, **Art. M3460/M3460A** Classic AG Thigh High Class III open and closed toe, **Art. M3460S/M3460AS** Classic AG Thigh High Short version Class III open and closed toe, **Art. M3470/M3470A** Classic AGH Thigh high w/lace Class III open and closed toe, **Art. M3470S/M3470AS** Classic AGH Thigh high w/lace Short version Class III open and closed toe, **Art. M3480/M3480A** Classic AT Pantyhose Class III open and closed toe, **Art. M3480S/M3480AS** Classic AT Pantyhose Short version 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. M3480OS/M3480OAS** Classic AT Pantyhose Short version Class III with front and back opening with open and closed toe.

**Relaxsan Medicale Soft**

*BASIC UDI-DI Code - 83009610011ME*

*NSIS: 2249015*

**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. 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.

**Relaxsan Medicale Cotton**

*BASIC UDI-DI Code - 83009610012MG*

*NSIS: 2249015*

**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. 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.

**Relaxsan Medicale Silver**

*BASIC UDI-DI Code - 83009610013MJ*

*NSIS: 2249015*

**Art. M2250A** Silver AD Knee High Class II.



**Relaxsan Medica Ecofiber**

BASIC UDI-DI Code - 83009610018MU

NSIS: 2249015

**Art. M1550** Ecofiber AD Knee High Class I closed toe, **Art. M1550S** Ecofiber AD Knee High Short version Class I closed toe.

**Relaxsan Medica Classic Cotton**

BASIC UDI-DI Code - 83009610014ML

NSIS: 2249015

**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 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.

**Relaxsan Medica Classic Arm sleeve**

BASIC UDI-DI Code - 83009610015MN

NSIS: 2249015

**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**

BASIC UDI-DI Code - 83009610016MQ

NSIS: 10314-10256-10262-10245-10301-10299-10305-10297-10258-10303-10263-10296-10307-10309-11308-10248-10246-10253-10252-286755-286751-10275-10277-286764-10291-10289-10278-10311-10279-10254-10251-10315

**Art. 1200** Men's half sleeve elasticized undershirt with knitted-in band, **Art. 1200D** Men's half sleeve elasticized, double-back undershirt with knitted-in band, **Art. 1300** Men's wide shoulder elasticized vest with knitted-in band, **Art. 1400** Men's long sleeve elasticized undershirt 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. 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 poly-extensive 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.

**RelaxSan Postura**

*BASIC UDI-DI Code - 83009610017MS  
NSIS: 1991273*

**Art. 4070-RP** Posture Reminder T-Shirt for Men, **Art. 6070-RP** Posture Reminder T-Shirt for Women.

Intended for graduated compression, risk class I (Non Sterile), in accordance with rule 1 of Annex VIII of EU Regulation 2017/745, declares under its sole and exclusive responsibility that these devices:

- comply with the safety and performance requirements and the provisions of Regulation (EU) 2017/745 and subsequent amendments. as per the Technical File filed at the company.
- Common Specifications have not been used for the compliance of the aforementioned medical device.
- are manufactured in accordance with the Quality System, which meets the requirements set out in Annex II + III of the aforementioned Regulation.

Casaloldo (MN), 20/01/2023

**CALZE G.T. S.r.l.**

**CALZE G.T. s.r.l.**

Sede Legale e Produzione  
Via Castel Goffredo 31/33, 46040 Casaloldo (MN)  
Sede Amministrativa ed Operativa  
Strada per Cadimarco 44, 46041 Asola (MN)  
P.IVA e C.F. 01280780203 - REA MN 155014

Cristiano Gorgaini  
Legal Representative