

4th September 2025

### Manufacturer's Declaration of Compliance

We, **INTERmedic, S.A.** (Spain), hereby declare that the CO<sub>2</sub> laser **SILKLASE™** has the following characteristics:

1. The **SILKLASE™** laser system provides **three operating modes** – *Fractional Scanner, Surgical Mode and Derma Mode*. All necessary handpieces and/or other elements required to perform the procedures are included in the system configuration, making it a complete and integrated laser platform.

Each of these operating modes is further differentiated into **Continuous, Pulsed, SuperPulse and FinePulse** sub-modes. The laser operates in fractional mode **only when used together with the fractional scanner; without the scanner, the fractional mode cannot be performed.**

2. The **SILKLASE™** laser system includes **integrated treatment programs for skin lesion removal**, such as ablation, cutting, excision, vaporization. These programs consist of pre-configured procedure parameter sets, ensuring optimal treatment outcomes (including power, pulse duration, repetition rate, fractional coverage, and many other settings).

The system allows removal or treatment of a wide range of skin lesions and conditions, including but not limited to:

- Actinic keratosis, actinic cheilitis
- Seborrheic keratosis
- Nevus (moles)
- Fibromas and fibroids
- Syringomas, xanthelasmas, milliums
- Molluscum contagiosum, warts
- Sebaceous cysts
- Benign non-vascular tumors
- Epitheliomas
- Infectious and inflammatory lesions
- Keloids, scars (including post-acne)
- Wrinkles, stretch marks, dilated pores
- Non-surgical eyelid retraction and rejuvenation procedures.

3. The **SILKLASE™** aiming beam has an output of  $\leq 5$  mW, and its intensity is **adjustable from 0% to 100%.**

Don't hesitate to contact us if you need any additional information.

INTERmedic Arfran S.A.  
Mr. Xavier Arcusa  
CEO

**INTERmedic**  
Parc Tecnològic del Vallès  
C/ Boters 5-10  
Tel.: (+34) 932 656 661  
Fax: (+34) 932 454 806  
08290 Cerdanyola del Vallès  
Barcelona-Espana  
C.I.F. A-43533090

**Rašytinis patvirtinimas / paaiškinimas  
Gamintojo atitikties deklaracija**

**Rugsėjo 4d, 2025**

Mes, **INTERmedic, S.A.** (Ispanija), patvirtiname, kad CO<sub>2</sub> lazeris **SILKLASE™** turi šias savybes:

1. **SILKLASE™ lazerio sistema** turi tris darbo režimus – *frakcinį (naudojant frakcinį skenerį), chirurginį ir derma režimą*. Visi reikalingi antgaliai ir/ar kiti elementai, būtinai procedūroms atlikti, yra įtraukti į sistemos komplektaciją, todėl tai yra pilna ir integruota lazerio platforma.

Kiekvienas iš šių darbo režimų papildomai diferencijuojamas į **nuolatinį (Continuous), impulsinį (Pulsed), SuperPulse ir FinePulse** potipius. Lazeris frakciniu režimu veikia tik naudojant frakcinį skenerį; be skenerio frakcinis režimas negali būti atliekamas.

2. **SILKLASE™ lazerio sistema** turi integruotas gydymo programas, naudojamas odos darinių šalinimui, tokias kaip abliacija, pjovimas, ekscizija, vaporizacija.

Šios programos yra sudarytos iš anksto sukonfigūruotų procedūrų nustatymų rinkinių, užtikrinančių optimalų gydymo rezultatą (įskaitant galią, impulso trukmę, pasikartojimo dažnį, frakcinį padengimą ir daugelį kitų parametrų).

**Sistema leidžia šalinti ar gydyti platų spektrą odos darinių ir būklių, įskaitant, bet neapsiribojant:**

- Aktininė keratozė, aktininis heilitas
- Seborėjinė keratozė
- Neviai (apgamai)
- Fibromos ir fibroidai
- Syringomos, ksantelazmos, miliumai
- Moliuskai, karpas
- Riebalinės cistos
- Gerybiniai ne kraujagysliniai navikai
- Epitelomos
- Infekciniai ir uždegiminiai pažeidimai
- Keloidai, randai (įskaitant po aknės)
- Raukšlės, strijos, išsiplėtusios poros
- Nechirurginis vokų patempimas ir atjauninimo procedūros.

3. **SILKLASE™ taikiklio spindulys** turi mažiau nei **5 mW** galią, o jo intensyvumas reguliuojamas nuo **0 % iki 100 %**.

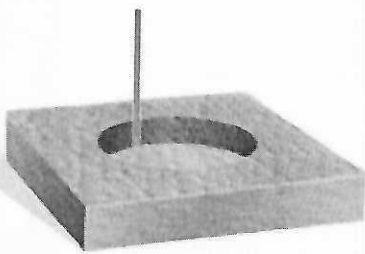
Intermedic S.A.  
Misteris Xavier Arcusa  
Generalinis Direktorius

CO2 laser multidisciplinary platform

## Optimal for day to day in **consultation** or **operating room**

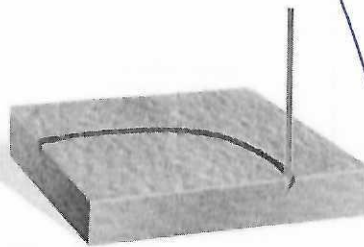
A unique tool with  
maximum versatility

- Aesthetic lesions
- Warts
- Actinic keratosis
- Seborrhoeic keratosis
- Xanthelasma
- Molluscum



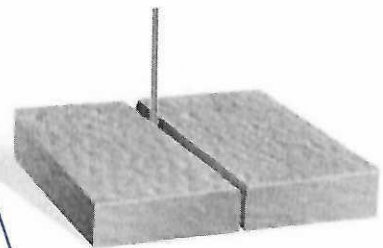
**ABLATION**

Abliacija/koaguliacija



**CUTTING**

pjovimas



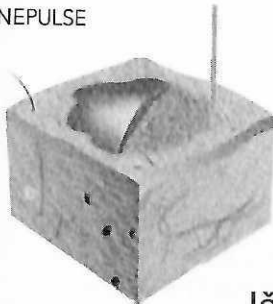
**EXCISION**

Ekscizija

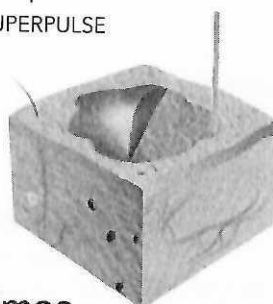
...and absolute precision

- Precise tissue vaporisation
- Highly predictable depth of effect
- Exquisite thermal control

Superficial  
FINEPULSE



Deep  
SUPERPULSE



Išgarinimas  
**VAPORIZATION**



Heat delivery to tissue and depth of penetration can be controlled to ensure maximum efficacy and best clinical results, while limiting side effects and recovery time. Thanks to the FinePulse emissions in fractional mode and the random scanner system, the thermal effect can be controlled to the nearest micron.

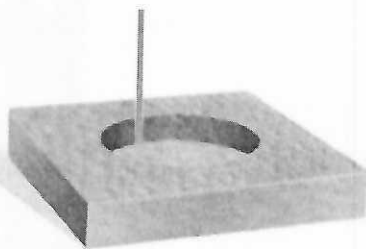
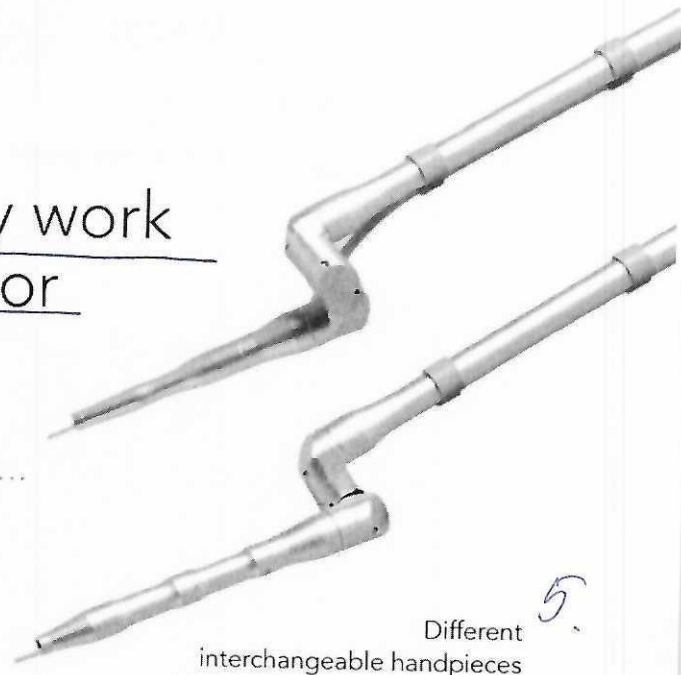
5p.  
Frakcininė  
mezoterapija



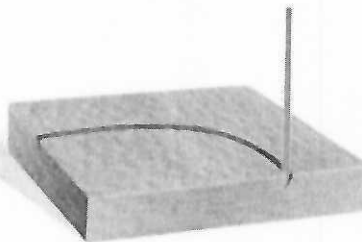
# Optimum for day-to-day work in the consulting room or operating theatre

A unique tool with maximum versatility...

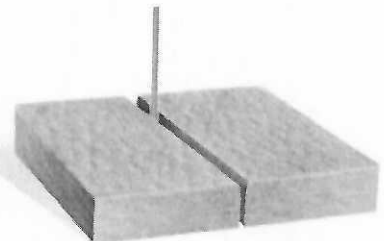
- Aesthetic injuries
- Warts
- Actinic keratosis
- Seborrheic keratosis
- Xanthelasma
- Molluscs



ABLATION



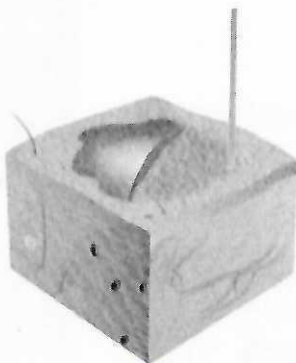
CUTTING



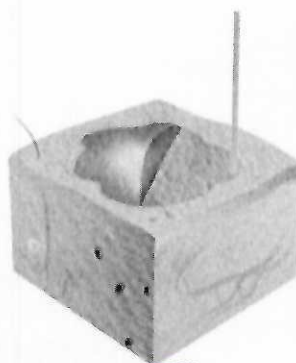
EXCISION

...and absolute precision

- Precise tissue vaporisation
- Highly predictable depth of action
- Excellent thermal control



Superficial FINEPULSE



Deep SUPERPULSE

VAPORISATION

Heat delivery to the tissue and penetration depth can be controlled to ensure maximum effectiveness and the best clinical outcomes, while reducing side effects and recovery time. Thanks to its FinePulse emissions in fractional mode and random scanner system, the thermal effect can be controlled with micron precision.



## VII UNIT PARTS

### EQUIPMENT LIST

Following lists enumerate standard, optional and spare pieces of the system:

#### STANDARD ACCESORIES

Following parts are included in the System: 5p.

- CO2 Laser equipment.
- Power supply cable.
- 3 protector goggles. 7. Apsauginiai akiniai 3 vnt.
- 1 corneal protector.
- Foot-switch.
- Fractional scanner. *Sudeiktine lazerio dalis*
- Support for scanner.
- Set of hand-pieces for CO2 laser surgery, FINE CUT and HAEMOSTATIC CUT (focal F-50 and F-100).
- Articulated arm.
- Security key.
- External power meter, optional depending on model.
- User's manual.
- Clinical workbook. 6p.

#### MULTISCAN STRAIGHT HAND PIECES AND ACCESSORIES

- MultiScan.
- Support for scanner.

#### DERMATOLOGY ACCESSORIES

Dermatology set. Supplied total o partial depends on the model:

- Set of cones with integrated lenses for scanner fractional (spot 500 $\mu$ m and 190 $\mu$ m).
- Pin backstop.
- Circular backstop.



without the need to press the foot-switch again with a selectable pause time (from 1 to 5 seconds). Frequency runs between 1 and 100Hz.

- **Aiming Beam (%)**. Adjust aiming beam intensity from 0 to 100%.
- **NO AIMING BEAM WHEN FIRING**. This button is on the right side of the screen. Its function is to turn off the guide when the laser is firing.

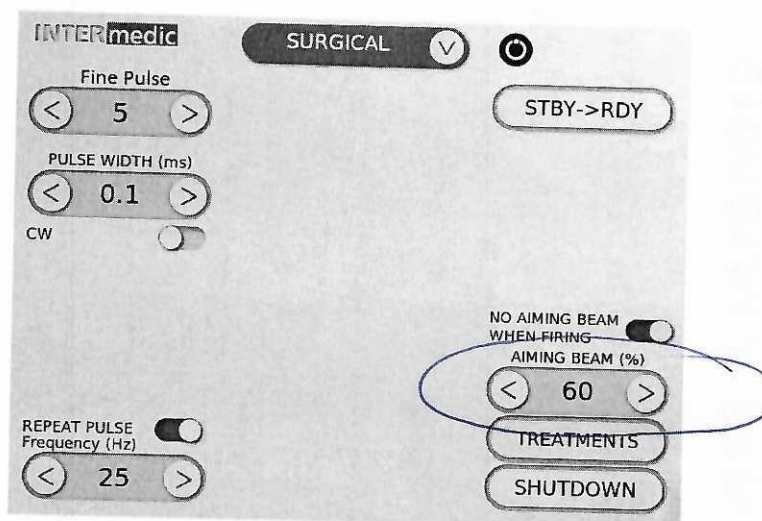


Figure 39: Surgical Fine Pulse Mode.

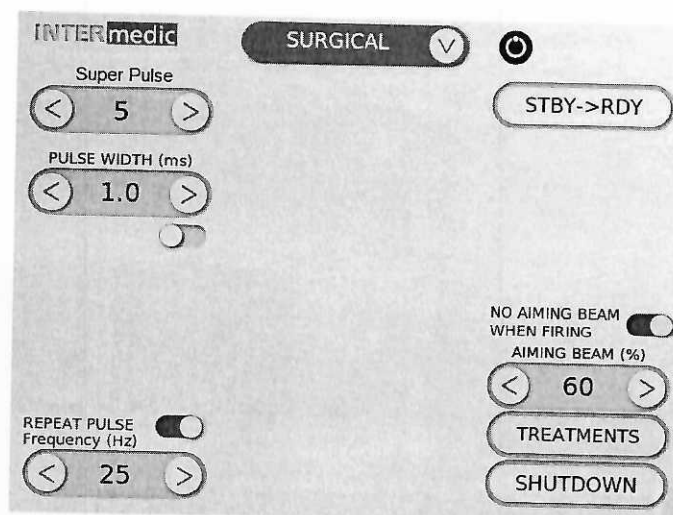


Figure 40: Surgical Super Pulse Mode.





## DERMA MODE

### SYSTEM CONTROL

- **Power (W).** Laser beam power selection for pulses longer than 2.5ms. From 5 to 20W in steps of 1W.
- **Pulse width (ms).** Three thresholds:
  - **FINE PULSE** [from 0.1ms to 0.9ms]. In this pulse width range there are 5 selectable power levels. From 5 (maximum level) to 1 (minimum level (30% of maximum power level, value 5). See figure 45. maintain a predefined specified relationship.
  - **SUPER PULSE** [from 1.0ms to 2.4ms]. In this pulse width range there are 5 selectable power levels. From 5 (maximum level) to 1 (minimum level (30% of maximum power level, value 5). See figure 46. Pulse duration and power maintain a predefined specified relationship.
  - **PULSE**
    - \* For spot 500 [from 2.5ms to 6ms]. Power selection between 5 to 20W, pressing the arrows near the option square (figure 47).
    - \* For spot 190 [from 2.5ms to 10ms]. Power selection between 5 to 20W
- **Energy Density.** This panel shows the calculated value of applied energy over the target zone. It varies depending on the selected energy options.
- **Stacking Repeats.** Selection number of pulse repetitions (until 5). The unit will emit some consecutive pulses of the selected duration. Note: 1 repetition is equal to 2 emissions; 5 repetitions are equal to 6 emissions.
- **Repeat Scanner.** This option enables the selected pulse to be repeated without the need to press the foot-switch again with a selectable pause time (from 1 to 3 seconds).
- **Aiming Beam (%)**. Adjust aiming beam intensity from 0 to 100%.
- **NO AIMING BEAM WHEN FIRING.** This button is on the right side of the screen. Its function is to turn off the guide when the laser is firing.

Remember prefixed parameters appear on the screen in soften lines.

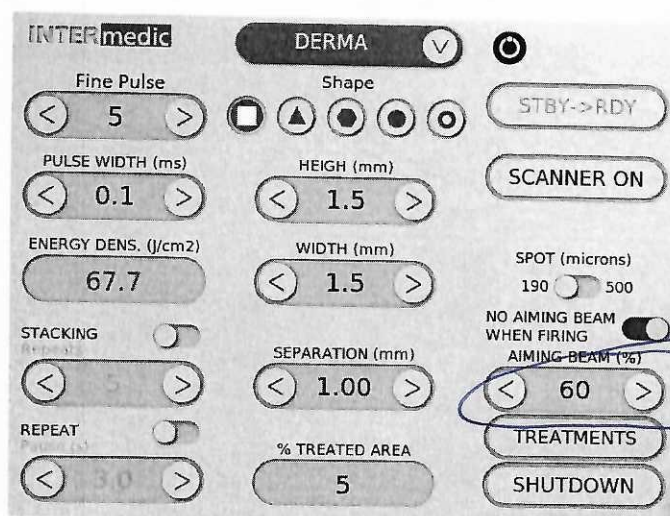


Figure 45: *Derma Fine Pulse Mode.*