

# **Combination Therapy**



### **History of LUMARO®**

Two friends, Ing. Bernhard Wurnitsch, BEd and Andreas Pangratz, MBA, were surching together for supporting healing methods to help a family member.

Many discussions with medical professionals and therapists in treatment and rehabilitation facilities, such as KH Waiern / Diakonie de la Tour in Austria, confirmed the two men in the decision. Together with the medical director, Prim. Dr. Gaugeler and Mag. Salem (University of Klagenfurt, Austria) they started to develop the

Energy Regeneration System "LUMARO"

With the planning and construction of several prototypes followed the steady improvement of the medical device. After completing the medical test series, the two friends started in 2013 the Company Valetudo GmbH in Austria. In 2015, the classification was carried out in the Austrian Register as a medical device.

The professional art & lighting designer Wolfgang von Zoubek, supplemented in 2017 with his extensive knowledge of the impact of light and music LUMARO to the final version:

A Combination therapy

light and colour, warmth, music and aroma

Valetudo GmbH Sandra Barta

Albrechtsgasse 111 A-2500 Baden

www.valetudo.at

Art Light & Design ALD GmbH Wolfgang von Zoubek

Höggerloh 1 D-85646 Anzing

www.ald.ae



# What is LUMARO?

- System to regenerate and increase the well-being of body and mind
- Medical device manufactured in Austria for combination therapy
- > Each component has been scientifically researched and tested
- Individual programs can be set to the individual user
- To produce Vitamin B, UVB light can be added before the session

### **LUMARO** combines

Light therapy protects the immune system

Music therapy promotes harmony

Aroma therapy calming effect on the nervous system

Warmth therapy relaxes the muscles







# When you feel

- overstressed
- exhausted
- overburdened
- tired
- overstrained



# **LUMARO**

# **Combination Therapy**

- reduces stress
- strengthens the immune system
- calms the nervous system
- relaxes the muscles
- regenerates the whole organism





**Light Therapy** 

The colored light is added through the skin and the optic nerves in our organism. Color vibrations pass directly through the cells into our nervous system and affect the immune system



Music Therapy

Over the high quality Bose Soundsystem the specially selected compositions accompanies each individual program



Aromatherapy

The fragrance of naturally pure essential oils gives each program its individual note. The aroma essences are specially adapted to the different applications



Warmth Therapy

The body sinks into a "mattress" filled with warm quartz sand. Radiant heat ensures pleasant relaxation of the entire musculoskeletal system and the muscles



# **LUMARO**

# extends your features

- in the Medical Spa and Wellness Hotel
- in the surgery / clinic
- in the rehabilitation and therapy center
- helpful for reducing stress
- in lack of light (Vitamin D-deficiency)
- > pregnant women
- toddlers / adolescents (ADHD-syndrome)
- > seniors (joint pain)
- useful for all ages without restriction
- duration 1 session:35 min with UVB Light25 min without UVB Light
- during session no staff needed







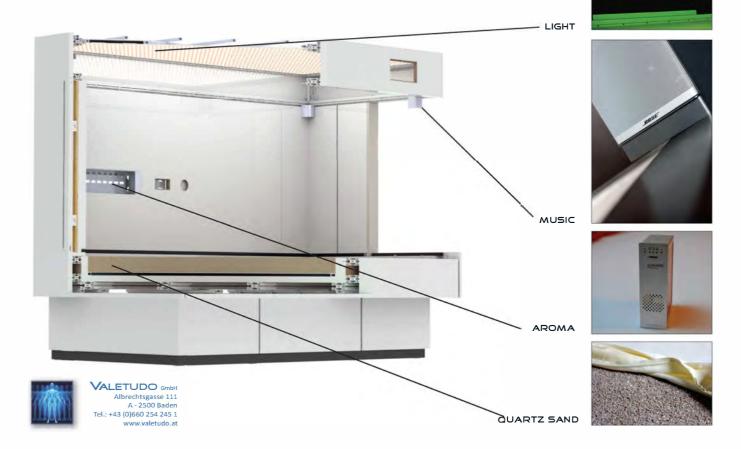






# LUMARO

ORCHESTRA OF SENSES





# LUMARO Combination Therapy



High-quality LED panel consisting of 16,740 RGBLEDs. Each individual LED contains the full color spectrum of 16.7 million colors and depending on the wavelength up to 20,000 lux in LED technology. Color transitions occur continuously and synchronously with the music.

Light



The Bose sound system consists of two magnetic shielded satellite speakers and a Subwoofer. Through the patented Integrated Signal Processing System delivers it lifelike top sound at almost every volume with a power consumption of 60 watts

Music



The aroma unit is equipped with 10 fragrance cartridges. These are refillable and replaceable. The flavors used meet the highest Certification standards (according to ANFOR). A cartridge contains 50 ml and is enough for about 270 applications. The Level of each cartridge is visible by the status indicator.

**Aroma** 



Warmth

The lying area (mattress 2 x 1 m) is filled with quartz sand (Grain size 2 - 3 mm). It is covered with a wipedisinfectable material. The integrated sensor-controlled and adjustable heating system (300 watts) delivers consistently pleasant warmth. Through the specially developed substructure, the user can feel an individual, ergonomic and spine-sparing storage.



# **LUMARO**

# **Combination Therapy**

# The 4 Therapies at a glance

#### Light and color therapy

Light is life - it strengthens the immune system, promotes concentration and creativity. Light increases the body's own production of vitamin D. In color therapy, the effects of different colors (absorption through the skin) play an essential role for the human psyche eg. at SAD (seasonal conditional winter depression), stress and primarily sleep disorders and jet lag

#### Music therapy

Music is vibration - every cell in our body follows its own rhythm and is in harmony, when we feel comfortable. By listening to music, we sharpen the self - awareness as well as the introspection. Music therapy is also used in ADHD (attention deficit hyperactivity disorder), Anxiety disorders, or just to feel comfortable.

### **Aromatherapy**

Is a traditionally proven method and is considered the oldest form of healing Therapy at all. Essential oils have highly effective molecular properties. They exceed the blood-brain barrier. Aromas enter the limbic system via the olfactory nerve. In connection to the hypothalamus, they act on our vegetative Nervous system. Essential oils can be antiseptic and disinfectant invigorating, soothing or balancing.

# Warmth therapy

Heat gives relaxation - bedded on warm quartz sand, the musculature will regenerate. The metabolism is stimulated, the blood circulation and the oxygenation of the cells improved. Movement problems, headache and body aches, rheumatic complaints and many more are gently soothed. Especially in sports medicine, the warmth therapy is increasingly used.

"To calm down, we do not have to think, but dreaming "



# LUMARO Light Therapy and

# Light Therapy and Vitamin D deficiency



Unlike other vitamins, vitamin D can be produced by the human body itself, under the influence of sunlight: The built-up cholesterol in the skin is thereby converted into the provitamin D. This "light hormone" passes through the blood into the liver, where it is stored as vitamin D3. In another step, it can be converted to active vitamin D3 in the kidney and other organs.

### Why are we increasingly suffering from lack of light?

The last decades, our everyday way of life has changed totally. We mainly stay in closed rooms and this interferes the body's own Vitamin D formation. This important process has an impact on our whole organism. Lack of light, therefore also the vitamin D deficiency, has fatal consequences for our physical and mental Health: bone metabolism, Muscle weakness, fatigue, depressive moods and sleep-disorders

- Children hardly play outdoors anymore, leisure times take place increasingly indoors instead of staying outside during the day
- Working adults usually stay under artificial light
- Seniors often suffer from movement restrictions and prefer to stay inside the home: The vitamin D depot is dwindling
- Fear of sunburn: Before every little step in the nature, high sun protection is applied on the skin: The Vitamin D formation suppressed

Together with medical professionals and scientists we have given our best to establish the light therapy in modern health care system in combination with color, music, aroma and warmth

A body with good filled vitamin D depot prevents deficiency and illness.

We feel vital and balanced







# Quarzsand

**LUMARO** is a medical energy and regeneration system.

It is used both in the clinic / surgery as well as in the Medical Spa. Produced in Austria, most materials are originally from Austria.

The quartz sand is an integral part of **LUMARO**.

**LUMARO** allows a combination of 4 therapies: Light/color, aroma, music and warmth

The heat therapy is carried out by the warm quartz sand. It is characterized by its special grain - the so-called Quartz grains. Their high degree of rounding and the small grain size achieves the best effect in the **LUMARO**.

The positive curative effect is explained by the fact, that the steadily heated sand will relax the musculoskeletal system.

Quartz sand is a perfect storage medium and gives off the heat ideal long-lasting.

The gentle quartz sand heat therapy has been used for many years. The field of applications is at following areas: rheumatism, joint-, bone and muscle pain of different origin, at stress, as burn-out prophylaxis, muscle relaxation and many more.

The relaxing effect of the warm quartz sand not only helps to find peace and serenity, but in particular stimulates the body's immune system to become active again to cure.

The body stores the heat for many hours. The patient can feel the positive effect of the therapy until long hours after the session

# **LUMARO** ®

# **Version S**



# Version A open



# Version R closed with door





# 3 versions / technical data

# Lumaro S

This version is placed in an existing room. The room should be darkened. The fronts are available in different colors and materials (wood variants, technoglass, aluminum, ...)

Length x width x height =  $2180 \times 1177 \times 1700 \text{ mm}$ Dimensions:

Power supply: 230V / 50 Hz over safety socket,

MPG version:

protection with 13A med. Certified safety isolating transformer

Weight: inclusive quartz sand 490

Height bench: kg 680 mm

# Lumaro A

This version is placed in an existing room. The room should be darkened. The fronts are available in different colors and materials (wood variants, technoglass, aluminum, ...)

Dimensions: Length x width x height =  $2180 \times 1177 \times 1700 \text{ mm}$ 

power supply: 230V / 50 Hz over safety socket,

MPG version: protection with 13A med. Certified safety isolating

transformer inclusive quartz sand 560 kg

Weight: 680 mm Height bench:

# Lumaro R

This version is delivered as a whole room with a lockable door. The fronts are available in different colors and materials (wood variants, technoglass, aluminum, ...)

Dimensions: Length x width x height = 2300 x 2300 x 2100 mm

Power supply: 230V / 50 Hz over safety socket,

MPG version:

protection with 13A med. Certified safety isolating transformer

Weight: Height inclusive quartz sand 1600 kg

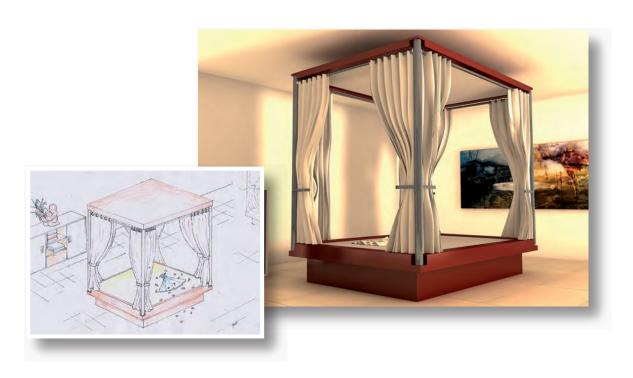
bench: 680 mm



# **LUMARO**



The energy and regeneration system can be individually designed on exclusive customer demand



Our example for your individual solution (Version) **LUMARO I** 



# Different looks for your LUMARO









# References from our partners / customers



Kepler University Hospital Med Campus III. Krankenhausstraße 9 4021 Linz / Austria www.kepleruniklinikum.at

In the Kepler University Hospital - Neuromed Campus - Mental and nervous system disorders are treated . Neurological Psychiatric Gerontology is treating mainly older patients with an average age around 70 - 80

Similarly patients with diseases such as dementia, depression, fears, movement disorders and so on and in addition their family members are cared for.

Various dysfunctions or disorders of the brain may interfere with everyday activities, so our job is to treat changes in advanced age.

The therapy takes place on several levels by for example medical supervision by the doctor, clinical psychology, music therapy as well as additional LUMARO sessions with aroma, music, heat and light therapy through the UVB implementation.

As a result, the body independently produces vitamin D, which is urgently needed to stop or even alleviate existing diseases and also to preventively intervene.

Restless patients find peace and relaxation. Our staff also use a session as a way to recharge their batteries.

The use of LUMARO is done regularly and continuously as well by patients and the staff. It helps to restore and maintain the health and to prevent diseases.

A sufficient level of vitamin D is a prerequisite for maintaining our health and helping to prevent mental diseases .

It support the organism to be and stay strong and healthy until senior age.





Dr. Alexander Deimel Braitner Str. 109/1 2500 Baden, Österreich www.alexander-deimel.at

#### Stress and vitamin D - a connection?

Malaise? Bad sleep? Burn-out syndrome?

Tachycardia? High blood pressure? Vitamin D deficiency?

#### How does chronic stress affect our immune system?

Chronic stress arises when over a long period of time long-term load is present. Constant and chronic stress makes you more likely to get sick. Viruses, bacteria and germs have less counter-defense than in the relaxation phase.

Chronic stress reduces the vitamin stores in the body very fast .

The vitamin D level drops and the result is visible only in later episode and noticeable by various symptoms such as general malaise, bad sleep, palpitations, incipient burnout syndrome and many more.

It often only becomes clear that you are suffering from exhaustion or burnout syndrome when you are already in the middle of it.

Through various medical examinations such as a special long-term ECG and a saliva sample and a targeted blood sample and the determination of various blood levels and vitamin value in the blood (vitamin D, vitamin C, vitamin B, vitamin K, amino acids, ...) stress levels can be clearly measured and made visible.

My basis treatment is conventional medicine. In addition, I also incorporate complementary medical techniques in my treatment.

Together, this completes the treatment methods for my patients so that they can live again a balanced and relaxed life with filled vitamin stores and, above all, enjoy their life.

#### To my treatment concept belong

- > a nutritional consultation
- a relaxation concept (by LUMARO)
- Replenishment of empty vitamin storage in the body both orally and through regular UVB-LED therapy sessions in the LUMARO regular exercise in the fresh air
- > Lifestyle advice







Dr. Dobrovits Michael
FA für Urology und Andrology
Martinstrasse 91/8A
1180 Wien
www.drdobrovits.at

As a treating urologist and andrologist, it is particularly important for me to offer my patients an extensive and comprehensive medical diagnostics.

In many urological diseases, relaxation and light therapy as a supplement to conventional medicine has a very positive effect and also supports my treatment methods.

Irrespective of irritable bladder, prostatitis, desire for children and much more. Especially men often suffer from erectile dysfunction due to permanent stress and overload. An additional therapeutic treatment in my ordination with **LUMARO** has proven to be very helpful and supportive. Stress, congestion and depression, as well as many other problems, can be treated well with this innovative four-step therapy.



Dr. Salem Ingrid Clinical and health psychologist Abteilung für klinische Psychologie, Psychotherapie und Psychoanalyse der Alpen-Adria-Universität Klagenfurt wwwg.uni-klu.ac.at/psy

former psychologist director in public Krankenhaus in Waiern

Relax, switch off and let go: this is of paramount importance for patients with psychosomatic illnesses.

The combination of light and color, music, warmth and aromas helps patients to perceive with all their senses and to get into a phase of absolute rest, relaxation and security

Desirably, the patients can internalize this form of relaxation and take it into their everyday life afterwards.

Joie de vivre, creativity and mental stability increase again.

The applications can be Start independently from the patients after fixed deadlines and are therefore an integral part of our therapy offer.

At the same time, the results are currently flowing into a representative double-blind study. This study compares various methods of relaxation to scientifically prove the efficacy of LUMARO. Duration of the study about 2 years.





Prim. Dr. Richard Gaugeler

Medical director of the hospital Waiern, Austria

Diakonie de la Tour

www.diakonie-delatour.at

In an effort to familiarize our patients with innovative and effective methods of relaxation, we have been offering for some years now - in addition to other established procedures, such as Jacobson or biofeedback - also **LUMARO**.

Patients of all ages give us positive feedback and take advantage of the offer even after their inpatient stay as part of our outpatient follow-up care projects

In cooperation with the VALETUDO company, we have succeeded in taking into account the special needs of elderly people as well as the hygienic standards required in the hospital



Prim. Dr. med Henry Puff, MBA Specialist f. Orthopedics u. orthop. Surgery Medical Director

www.humanomed.at/kur-rehabilitation-althofen

Based on the scientifically founded biological phenomena, equipped with the repertoire of modern high-tech electronics, the energy and information medicine has great possibilities.

technical applications of physical signals of various kinds such as light, colors, sound waves and so on, can now be used for both diagnostic and therapeutic purposes.

Where there is color must be light, where light is, life is.

Without light and colors no life! This energy and information on the medium of light allows us a precise and subtle access to control levels of the organism and allows not only the detection of pre-stages of a disease, but, above all, the direct intervention on healing processes in many diseases and, above all, after surgical interventions.





Mag. Gernot Ogris

psychologist
Child and Family Care
Carinthia / Austria

Especially in this day and age, children and adolescents are finding it increasingly difficult to concentrate. Those who are not ready can usually only learn with great effort. It is known that e.g. Music by Mozart has a performance-enhancing effect, since the stored material is much easier to recall due to the relaxation.

- 1. Relaxation
- 2. Learning
- 3. Regeneration resting phase for mind and body

We noticed positively that children and adolescents at retrieving the learned for example examine situations on this regeneration phase and thus master the respective exam calmer and more relaxed. This positive effect can be seen in many interviews and lectures in front of many people. The self-confidence increases enormously.



Dr. med. Alexander Deimel Internist, Complementary Medicine Baden / Austria

When using a method of thinking or experiencing to bring about changes in the body, one speaks of "Mind / Body Medicine" or complementary medicine (e.g., by relaxation techniques).

**LUMARO** works as an ideal supplement to conventional medicine to provide the body with rest and relaxation as well as a cooldown phase. Relaxation relieves the strain on the muscles, which in turn reduces physical and emotional tension and relieves stress. Thus, hypertension, metabolic problems, digestive problems, migraines, tension and much more can be positively influenced..



# **LUMARO**

#### Combination therapy for oncologycal patients

Cancer is a disease that affects people holistically, so the choice of therapy should be chosen holistically and the disease itself should be treated holistically. In clinical oncology, patients are treted with surgery, Radiation Therapy and chemotherapy.

In addition, the immune system can be strengthened holistically - the sooner the better. The holistic treatment always includes the patient:

Through a healthy lifestyle with exercise and relaxation, healthy and wholesome nutrition, by detecting and avoiding stress. The connections between the psyche and the immune system can be used positively in the fight against cancer. All the more important is the conventional medical therapies complemented by measures from complementary medicine. The new beginning for a healthy lifestyle is best supported by LUMARO.

The intention of complementary cancer therapy with support from LUMARO:

- Strengthening and restoring the body's defenses
- ➤ Higher chances of recovery through relaxation therapy in the LUMARO
- Increase and maintain the quality of life
- Better coping with negative emotions such as depression and anxiety
- reduction of stress

The feeling of a walk in the forest,

Sunbathing on the warm sandy beach,

the scent of a spring meadow

and the chirping of birds at the beginning of spring

All these feelings can be recalled with a LUMARO session when the strength is lacking to actually walk in the forest or to enjoy a sunbath in the warm sand

With our combination therapy system LUMARO integrate this time-out into your cancer therapy, into your everyday life and thus into **your new life** 



The holistic healing and treatment concept in today's cancer therapy, in addition to the deep relaxation also includes the music therapy and aromatherapy, which are all given by the use of **LUMARO**.

One session of light bath in the **LUMARO** takes 25 minutes. In addition one can choose 10 minutes more with UVB light bathing (vitamin D production)

Most valuable time, in which exhausted energy storage are filled again and thus have a positive effect on the whole organism.

The use of relaxation techniques during ongoing cancer therapy or aftercare has been shown to increase the quality of life of cancer patients.

Anything that relieves tension, anxiety and cramping can also help cancer patients to process the disease better and to cope better with everyday life.

In modern oncological rehabilitation more emphasis is placed on relaxation techniques. The more relaxed the patient, the more successful the healing process and thus the increase in the quality of life.

Our individual **LUMARO** therapies as well as coordinated **LUMARO** therapy programs combine ancient and proven knowledge with the latest technology.

Supplementing with the **LUMARO** combination therapy is intended to be used as an adjunct to conventional medicine - but NOT as a replacement





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### **COMBINATION THERAPY with LUMARO**

## Experience reports of oncological patients

"It is not always easy to deal with such an illness, but LUMARO as a complementary therapy to conventional medicine has helped me to improve my well-being."

~

"I do not give up, I'm in a positive mood and I found the sessions in the LUMARO very pleasant - I could relax, listen to wonderful music and watch the changing light in between ,while my muscles relaxed in the warm sand. I always like to come back to this system for relaxation."

~

"I feel comfortable all around in this therapy device - it is warm, the music is pleasant and calm, I can switch off and occasionally relax so deeply that I fall asleep. The session takes 25 minutes – I can enjoy for a short while and do not think about my disease and how it will continue with me."

~

"LUMARO was recommended to me by a friend who has also been diagnosed with cancer. I tried it and was very moved and impressed after the first session. I will gladly come again."

~

"I am always very tired from the treatments and medications. Then I tried out LUMARO - there are also lightening activating programs and after that I felt a little better. The bright pleasant light, the different colors have done me very well."

~

"My doctor prescribed group therapy for me - but after being a loner, I've been struggling with that - that's why I tried out LUMARO - I can lie there alone, relax and sort my thoughts - I like the feeling of being safe - there I feel better."

~

"When I got the diagnosis of breast cancer 2 years ago, a world collapsed in me. My husband helped me a lot and accompanied me most possible.

Together with him I was able to try LUMARO - we were together in the unit and it was a very comfortable feeling - we were both excited and like to come regularly to relax".



## Combination therapy with LUMARO

### Reviews of patient

"After my severe stroke, I have been receiving multiple treatment for a long time." (Occupational Therapy, Physiotherapy) In addition, my family gave me therapeutic sessions in the LUMARO. The heat from the quartz sand and soothing music brought me back into balance. In my first sessions I hardly managed to lay on the therapy bed, but over time, I was always better able to put myself into it. Each treatment session brought me closer to my goal of living my life again as far as possible. "Johann, 73 years

"Many years of physiotherapy and an intervertebral disc surgery are behind me, but the pain was there every day. Then I became aware of LUMARO through a friend, and I made an appointment to work on it to convince myself and behold - immediately after the first session, I was pain free for several hours. Regular use is an indispensable part of my life now. "Maria, 41 years

"Obesity and resulting knee pain are already accompanying my life so far, but it could not go on. I was looking for a new, innovative kind of treatment - found it in the LUMARO. My knee pain disappeared after the first sessions and my weight problem I finally got under control. Through the effect of light, my mood has progressively improved. Consequently I am also able to regulate my eating habits. Now I am happy and satisfied all around. "Helga, 65 years

"Since childhood, I've had a serious muscle problem - no doctor could have helped me - everyone just said, I should be happy to be able to stand on my own feet. When depression and immobility became worse, a friend recommended LUMARO to me. I felt better after a while and was able to reduce my antidepressants. And the warmth helped me bring my underlying disease to an acceptable level and today I am satisfied as it is. "Johanna, 77 years old



Burnout - a diagnosis that I did not want to accept for a long time. A long career breakdown meant that I had to rethink my life and I knew one thing - I cannot go on like this. LUMARO brought me peace and relaxation during this difficult time and a lot of time for reflection. Now, I go back to work and treat myself with regular breaks in the LUMARO - this helps me not to become "backsliding". Wolfgang, 45 years

For years I went to the solarium - not because I wanted to get a tan, but because I need at least Septermber to May the light for my psyche. I had no alternatives to the solarium until I was made aware of LUMARO. Since then I'm laying now in the LUMARO and no longer use the solarium because I was increasingly afraid of skin cancer and my dermatologist definitely discouraged me from going to the solarium. Kathi, 32 years

I am a professional athlete and I know that the muscle is regenerated and built up mainly in the resting phase. Therefore, I treat myself after special workout as often as possible, and take a resting phase in the LUMARO. Alexander, 25 years

My child was almost constantly hyperactive and unable to calm down. I would never have thought that a 25-minute session would be possible. I almost did not recognize my child anymore, when I saw the gentle, happy and satisfied face I was close to tears. LUMARO made the impossible possible. Stefan & Julia, 10 and 37 years

I've been in treatment with my urologist for months. He once mentioned: therapy-resistant and advised me to try the LUMARO. I was so pleased after the first session that I immediately bought a block of 10 sessions. At the last medical checkup, he was almost speechless about how well I was doing and I'm really happy. Rudi, 55 years

Every year before the winter, I get my seasonal depression. The fog, the cold weather, the wind, the autumn, this "gray season" was partly unbearable for me - until I became aware of this innovative light therapy. The combination of light, heat, aroma and music are indescribable. Since then, I have no more problems with foggy, gray, gloomy, I have never gone so well in autumn / winter .Sabine, 35 years

My son has a learning and concentration weakness and is often afraid of school. We have already tried many therapies, but nothing could really help. After a few sessions at the LUMARO he felt better, the fear of the school was less, the concentration slowly increased.

Today he is definitely better and I am very happy about that! Mother of Christoph, 17 years

# Satisfied customers and the well-being of the patients are very important to us. Special thanks are due to:









#### **COMBINATION THERAPY with LUMARO** ®



Art Light & Design ALD GmbH info@ald.ae www.ald.ae









Datenauszug aus dem Österreichischen Register für Medizinprodukte gemäß § 67 (1) und (2) des Medizinproduktegesetzes (MPG) sowie gemäß Medizinproduktemeldeverordnung 2011

Excerpt from the Austrian Medical Devices Registry according to § 67 (1) and (2) Austrian Medical Devices Act (MPG) and according to the Enactment on the Registration of Medical Devices 2011

1. Zuständige Behörde / Competent Authority <sup>1</sup>	
Code der zuständigen Behörde / Competent Authority Code	AT/CA01
Bezeichnung der zuständigen Behörde / Competent Authority Name	Bundesministerium für Gesundheit Abteilung III/3- Arzneimittel und Medizinprodukte, Blut, Gewebe und Transplantationswesen
Adresse der zuständigen Behörde / Address of the Competent Authority	Radetzkystraße 2 A-1030 Wien / Vienna, Austria
Telefon / Telephone Number	+43 1 71100 4487
Telefax / Fax Number	+43 1 7134404 1590
E-Mail	meddev@bmg.gv.at
Website	http://www.bmg.gv.at/

2. Meldung zur Registrierung von Medizinprodukten gemäß § 67 MPG (Erstmaliges Inverkehrbringen) / Registration of Medical Devices according to § 67 MPG	
Datum der Registrierung bei der zuständigen Behörde / Date of registration 29.10.2015	
Datum der letzten Änderung / Date of last change	29.10.2015
Registrierungsnummer bei Erstregistrierung / Registration number at the date of the first registration	AT/CA01/M0009066-00
Aktuelle Registrierungsnummer (nach Änderung(en)) / Current registration number (after modification(s))	AT/CA01/M0009066-00

3. Zur Registrierung gemeldet von: / Reported by:	
Verantwortliche Person/Organisation (Melder) für das Inverkehrbringen /	Hersteller von Medizinprodukten / Manufacturer of Medical Devices
Status of person/organization (declarant) responsible for placing on the market	Sonderanfertiger von Produkten gem. § 30 MPG / Manufacturer of Custom Made Devices
	Hersteller von Systemen oder Behandlungseinheiten gem. § 33 MPG / Manufacturer of Systems or Procedure Packs acc. to §33 MPG
	Sterilisierer von Medizinprodukten gem. § 34 MPG / Sterilisation of Medical Devices acc. to § 34 MPG
	Bevollmächtigter des Herstellers / Authorised representative
	☐ Importeur / Importer
	☐ Vertreiber/Händler / Distributor
Registriernummer des Melders / Code of the declarant	AT/CA01/R002253-00
Name des Melders / Name of the declarant	alpha-tech
Straße und Hausnummer oder Postfach / Street, No.	Seegasse 47
Postleitzahl / ZIP code	9020

Seite 1 von 2

¹ Gemäß den Bestimmungen des Medizinproduktegesetzes (MPG, BGBl. I Nr. 657/1996 i.d.g.F) und den Richtlinien der Europäischen Union über Medizinprodukte besteht eine gesetzliche Verpflichtung Österreichs zur Führung eines Registers für Medizinprodukte und In-vitro Diagnostika (IVD). Gemäß § 1 (2) der Medizinproduktemeldeverordnung wurde für die Umsetzung dieses Gesetzesauftrags die Gesundheit Österreich GmbH (GÖG) vom Bundesministerium für Gesundheit mit der Einrichtung und laufenden Betreuung dieses Registers beauftragt. / According to the Austrian Medical Devices Act (MPG) and the corresponding EU Directives in Austria a legal obligation exists to implement a registry on medical devices and in-vitro diagnostics. According to the Enactment on the Registration of Medical Devices 2011 the Austrian Ministry of Health commissioned the Austrian Health Institute (GÖG) to set up and maintain the registry.







3. Zur Registrierung gemeldet von: / Reported by:		
Ort / City		Österreich
Staat / Country		Österreich
Kontaktperson: Name / Contact person: name		Ing., BEd Bernhard Wurnitsch
Telefon / Telephone Number		+43 650 4910885
Telefax / Fax Number		
E-Mail		alpha-tech@utanet.at
Website		keine
Sicherheitsbeauftragte/r für Medizinprodukte	Kontaktperson: Name / Contact person: name	Ing., BEd Bernhard Wurnitsch
gemäß § 78 MPG /	Telefon / Telephone Number	+43 650 4910885
Safety officer for Medical Devices acc. to	Telefax / Fax Number	
§ 78 MPG	E-Mail	alpha-tech@utanet.at
Im Falle einer Meldung als Bevollmächtigter, Importeur oder Vertreiber/Händler (falls	Name des ausländischen Herstellers / Name of the manufacturer outside the EEA	
	Straße und Hausnummer oder Postfach / Street, No.	
zutreffend): Angabe des ausländischen	Postleitzahl / ZIP code	
Herstellers außerhalb des Europäischen Wirtschaftsraumes / In case of registering as authorised representative, importer or distributor (if applicable), indication of manufacturer outside the European Economic Area (EEA)	Ort / City	
	Staat / Country	
	Kontaktperson: Name / Contact person: name	
	Telefon / Telephone Number	
	Telefax / Fax Number	
	E-Mail	
	Website	

4. Medizinprodukt / Medical Device	
Code des Medizinproduktes nach einer international anerkannten Nomenklatur für Medizinprodukte (z.B. UMDNS, GMDN) / Code from an internationally recognised nomenclature for medical devices	10-342
Falls vorhanden, Bezeichnung des Medizinproduktes nach einer international anerkannten Nomenklatur für Medizinprodukte / If available, code description from an internationally recognised nomenclature for medical devices	Bett (10-342)
Kategorie des Medizinprodukts / Category of Medical Device	Komplementärmedizinische Produkte
Art des Medizinprodukts / Medizinprodukte-Klassifikation / Type of Medical Device / Medical Devices Classification	Medizinprodukt Klasse 1
Produktname oder –fabrikat / Product name	LUMARO
Generischer Name / Generic name	Wärme- und Lichttherapiebett mit Musik- und Aroma

Nummer im Österreichischen Datenverarbeitungsregister (DVR) / Number according to the Austrian Data Processing Register: 0107085

Druckdatum / Print date: 29.10.2015







Datenauszug aus dem Österreichischen Register für Medizinprodukte gemäß § 67 (1) und (2) des Medizinproduktegesetzes (MPG) sowie gemäß Medizinproduktemeldeverordnung 2011

Excerpt from the Austrian Medical Devices Registry according to § 67 (1) and (2) Austrian Medical Devices Act (MPG) and according to the Enactment on the Registration of Medical Devices 2011

1. Zuständige Behörde / Competent Authority <sup>1</sup>		
Code der zuständigen Behörde / Competent Authority Code	AT/CA01	
Bezeichnung der zuständigen Behörde / Competent Authority Name	Bundesministerium für Gesundheit Abteilung III/3- Arzneimittel und Medizinprodukte, Blut, Gewebe und Transplantationswesen	
Adresse der zuständigen Behörde / Address of the Competent Authority	Radetzkystraße 2 A-1030 Wien / Vienna, Austria	
Telefon / Telephone Number	+43 1 71100 4487	
Telefax / Fax Number	+43 1 7134404 1590	
E-Mail	meddev@bmg.gv.at	
Website	http://www.bmg.gv.at/	

2. Meldung zur Registrierung von Medizinprodukten gemäß § 67 MPG (Erstmaliges Inverkehrbringen) / Registration of Medical Devices according to § 67 MPG	
Datum der Registrierung bei der zuständigen Behörde / Date of registration	29.10.2015
Datum der letzten Änderung / Date of last change	29.10.2015
Registrierungsnummer bei Erstregistrierung / Registration number at the date of the first registration	AT/CA01/M0009065-00
Aktuelle Registrierungsnummer (nach Änderung(en)) / Current registration number (after modification(s))	AT/CA01/M0009065-01

3. Zur Registrierung gemeldet von: / Reported by:	
Verantwortliche Person/Organisation (Melder) für das Inverkehrbringen /	Hersteller von Medizinprodukten / Manufacturer of Medical Devices
Status of person/organization (declarant) responsible for placing on the market	☐ Sonderanfertiger von Produkten gem. § 30 MPG / Manufacturer of Custom Made Devices
	Hersteller von Systemen oder Behandlungs- einheiten gem. § 33 MPG / Manufacturer of Systems or Procedure Packs acc. to §33 MPG
	Sterilisierer von Medizinprodukten gem. § 34 MPG / Sterilisation of Medical Devices acc. to § 34 MPG
	☐ Bevollmächtigter des Herstellers / Authorised representative
	☐ Importeur / Importer
	■ Vertreiber/Händler / Distributor
Registriernummer des Melders / Code of the declarant	AT/CA01/R002252-00
Name des Melders / Name of the declarant	Valetudo GmbH
Straße und Hausnummer oder Postfach / Street, No.	Albrechtsgasse 111
Postleitzahl / ZIP code	2500

Druckdatum / Print date: 29.10.2015

<sup>&</sup>lt;sup>1</sup> Gemäß den Bestimmungen des Medizinproduktegesetzes (MPG, BGBI. I Nr. 657/1996 i.d.g.F) und den Richtlinien der Europäischen Union über Medizinprodukte besteht eine gesetzliche Verpflichtung Österreichs zur Führung eines Registers für Medizinprodukte und In-vitro Diagnostika (IVD). Gemäß § 1 (2) der Medizinproduktemeldeverordnung wurde für die Umsetzung dieses Gesetzesauftrags die Gesundheit Österreich GmbH (GÖG) vom Bundesministerium für Gesundheit mit der Einrichtung und laufenden Betreuung dieses Registers beauftragt. / According to the Austrian Medical Devices Act (MPG) and the corresponding EU Directives in Austria a legal obligation exists to implement a registry on medical devices and in-vitro diagnostics. According to the Enactment on the Registration of Medical Devices 2011 the Austrian Ministry of Health commissioned the Austrian Health Institute (GÖG) to set up and maintain the registry.







Ort / City		Österreich
Staat / Country		Österreich
Kontaktperson: Name / Contact person: name		MBA Andreas Pangratz
Telefon / Telephone Number		+43 660 254 245 8
Telefax / Fax Number		+43 2252 254 245
E-Mail		ap@valetudo.at
Website		www.valetudo.at
Sicherheitsbeauftragte/r für Medizinprodukte	Kontaktperson: Name / Contact person: name	MBA Andreas Pangratz
gemäß § 78 MPG /	Telefon / Telephone Number	+43 660 254 245 8
Safety officer for Medical Devices acc. to	Telefax / Fax Number	+43 2252 254 245
§ 78 MPG	E-Mail	ap@valetudo.at
Im Falle einer Meldung als Bevollmächtigter, Importeur oder Vertreiber/Händler (falls	Name des ausländischen Herstellers / Name of the manufacturer outside the EEA	
	Straße und Hausnummer oder Postfach / Street, No.	
zutreffend): Angabe des ausländischen	Postleitzahl / ZIP code	
Herstellers außerhalb des Europäischen Wirtschaftsraumes / In case of registering as authorised representative, importer or distributor (if applicable), indication of manufacturer outside the European Economic Area (EEA)	Ort / City	
	Staat / Country	
	Kontaktperson: Name / Contact person: name	
	Telefon / Telephone Number	
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Produktname oder –fabrikat / Product name	LUMARO
Generischer Name / Generic name	Wärme- und Lichttherapiebett mit Musik- und Aroma

Nummer im Österreichischen Datenverarbeitungsregister (DVR) / Number according to the Austrian Data Processing Register: 0107085

Druckdatum / Print date: 19.03.2014

# EU-Konformitätserklärung / EU Declaration of Conformity

# alpha-tech

Engineering 4your success

Das nachfolgend beschriebene Medizinprodukt

The medical device described below

LUMARO "A" Energie- und Regenerationssystem

LUMARO "R" Energie- und Regenerationssystem

Туре

LUMARO "A" energy and regeneration system LUMARO "R" energy and regeneration system

Wärme- und Licht-Therapiebett mit Musik- und Aromabehandlungen Heat- and Lighttherapy bed with music and aroma treatments

Produkt behandlungen treatments Products

Produkt- MDD 93/42/EWG Annex IX Product klassifikation Class I classification

Artikelnummern 1213-1

1213-2 Article Numbers

UMDNS-Code 10-342 UMDNS Code

hergestellt von alpha-tech Manufactured by

Hauptstraße 19 8813 St. Lambrecht Austria

stimmt mit der Richtlinie des Rates zur Angleichung der Rechtsvorschriften der Mitgliedstaaten über Medizinische Produkte (93/42/EWG) bzw. deren letztgültigem Stand überein.

is in compliance with the European Council Directive on the approximation of the laws of the Member States relating to Medical Devices (93/42/EEC) or the last status thereof.

CE

Datum, February 2<sup>nd</sup>, 2014

Date,

Ing. Bernhard Wurnitsch Geschäftsführer/ Inhaber Ing. Bernhard Wurnitsch Managing Director/ Owner

#### **GISA**

# Bundesministerium für Wissenschaft, Forschung und Wirtschaft

#### Gewerbeinformationssystem Austria

Stichtag: 29.10,2015 Auszug mit aktuellen Daten – berechtigtes Interesse DVR: 0037257

Behörde: Bezirkshauptmannschaft Baden

GISA-Zahl: 28117520

#### DATEN ZUR GEWERBEBERECHTIGUNG

Entstehung: 29.10.2015

#### **GEWERBEINHABERIN**

Bezeichnung: VALETUDO GmbH

Rechtsform: Gesellschaft mit beschränkter Haftung

Firmenbuchnummer: 399545t

Anschrift: 2500 Baden, Albrechtsgasse 111

GLN: 9110018090601

#### GEWERBEWORTLAUT (Gewerbeart: reglementiertes Gewerbe)

Herstellung und Aufbereitung sowie Vermietung von Medizinprodukten, soweit diese Tätigkeiten nicht unter ein anderes reglementiertes Gewerbe fallen, und Handel mit sowie Vermietung von Medizinprodukten, eingeschränkt auf den Handel mit Medizinprodukten

#### STANDORT der GEWERBEBERECHTIGUNG

Entstehung: 29.10.2015 Gemeinde: Baden

Anschrift: 2500 Baden, Albrechtsgasse 111

#### GESCHÄFTSFÜHRER (gewerberechtlich)

seit 29.10.2015

Titel nachgestellt: MBA
Zuname: Pangratz
Vorname: Andreas

geboren am: 19.01.1968 in Steyr, Österreich

Geschlecht: männlich

wohnhaft in: 2500 Baden, Albrechtsgasse 111/2

Staatsangehörigkeit: Österreich Sozialversicherungsnr.: 2103190168



Dieses Dokument wurde amtssigniert.

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