

# SINFONIA PLUS (GSI+) DATASHEET



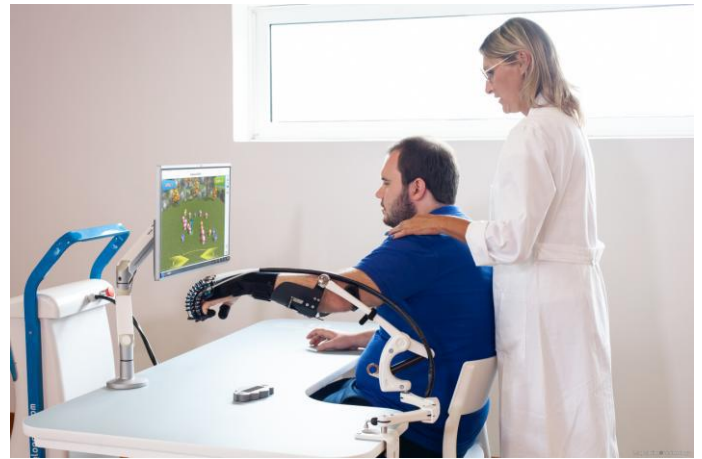
SINFONIA PLUS is the complete solution for the motor rehabilitation of the hand and upper limb and for the neurocognitive training. One only device able to offer both passive and assistive mobilization, advanced mirror therapies, functional tasks, serious games, cognitive exercises.

## Therapies:

|                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Passive mobilization of the fingers         | The movements are performed by a wearable glove which mobilizes the metacarpophalangeal, proximal and distal interphalangeal joints even without any active movements by the patient.                                                                                                                                                                                                                                              |
| Active-assisted mobilization of the fingers | Proposed exercises require the patient to initiate a motor task autonomously; the robotic glove follows the patient's activity and the motorized system intervenes to help only when necessary. Performance indicators give immediate feedback on the patient's degree of autonomy in flexion and extension.                                                                                                                       |
| Bimanual mirror training                    | The movements of patient's 'healthy' hand are recognized by the device and reproduced on the contralateral limb through the robotic glove. Compared to traditional Mirror Therapy, Sinfonia Plus enables one to go beyond the movement illusion: real motor training can be generated by the robotic glove on the hand with a motor deficit, increasing the rehabilitation potential.                                              |
| Therapist-driven mobilization               | Sinfonia Plus allows the therapist to wear a glove endowed with sensors to dynamically guide the movement of the passive mobilization glove on the patient's hand (master-slave logic). Timing and amplitude of finger flexion and extension movements are therefore managed by the operator in real-time, allowing the therapy to be constantly customized, depending on the patient's response and specific motor task proposed. |
| Interactive games for fingers               | Serious games motivate the patient to do his best to exploit his distal active ROM. Exercises train fist closing, hand opening, single finger flexion-extension, and tridigital pinch. Intuitive graphs at the end of the exercise show the patient and therapist the recorded trend, session after session.                                                                                                                       |
| Interactive games for the hand, wrist, arm  | The following active movements are detected by an optical sensor: <ul style="list-style-type: none"> <li>▶ Fingers flexion/extension;</li> <li>▶ Ulnar/radial deviation;</li> <li>▶ Wrist flexion/extension;</li> <li>▶ Pronation/supination;</li> <li>▶ Arm movements (up/down, left/right, back/forth).</li> </ul>                                                                                                               |
| Functional exergames                        | Artificial tendons mobilize patient's fingers while a sensor detects arm movements. The patient can actively move his arm with no gravity; when he reaches the target area, the rehabilitation glove intervenes to support flexion or extension of fingers.                                                                                                                                                                        |
| Cognitive exercises                         | Motor tasks are combined with cognitive exercises to train selective attention, divided attention, shifting abilities, visual-spatial exploration skills, memory, etc.                                                                                                                                                                                                                                                             |

## Further features:

|                                        |                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Virtual hand animation                 | Simultaneous 3D animation of the hand can be shown in different positions and from different points of view. Male and female models are available. Skin colour is adjustable. 3D animation involves the patient, facilitates his body awareness, stimulates neuroplasticity, helps him to maintain and rebuild the hand cortical representation. |
| Action-Observation Therapy             | Sinfonia Plus allows the execution of exercises based on the logic of AOT for the activation of mirror neurons. In this case, the session consists of two steps: first, the patient observes a motor task on the screen; once the visual preview is over, the rehabilitation glove supports the specific motor exercise performance.             |
| Functional exercises with real objects | Sinfonia Plus allows the execution of grasping and reaching exercises with real objects, often taken from everyday life and professional environment.                                                                                                                                                                                            |
| Weight compensation of the arm         | Sinfonia Plus includes two dynamic arm supports, that are adjustable according to the patient's weight and residual capabilities.                                                                                                                                                                                                                |
| Silicone gloves                        | Only a comfortable and lightweight glove on the patient's hand. The glove leaves the patient's palm and arm completely free. The glove is easy to wear and clean. It is supplied in 6 sizes XXS, XS, S, M, L, XL (Right/Left).                                                                                                                   |
| Soft robotics                          | Sinfonia Plus is inspired by soft robotics: the mobilization is performed by a set of "artificial tendons" and the rehabilitation glove allows, encourages and detects patient's active movements.                                                                                                                                               |
| Proprioceptive exercises               | Random mobilization sequences are available to perform exercises aimed at training the proprioception: the patient can close his eyes and try to call the finger mobilized by the glove.                                                                                                                                                         |
| Selective mobilization and pinches     | Sinfonia Plus allows all the combinations of fingers flexion-extension (e.g. single finger sequence, fist, counting, wave) and all the pinches.                                                                                                                                                                                                  |
| Customizable vocal guidance            | A customizable vocal guidance can give the patient the proper instructions during the therapy execution. Messages can be shown and/or read by the software.                                                                                                                                                                                      |
| Multi-sensorial stimulation            | The therapy can be composed of lots of exercises; each exercise can join to a specific song (mp3 file) and customized effects (musical notes, sounds, colors, variable hues).                                                                                                                                                                    |
| For all ages                           | Applicable on children and adults.                                                                                                                                                                                                                                                                                                               |
| Height-adjustable ergonomic table      | The height of the work surface - C-shaped to "embrace" the patient - is adjustable. It is suitable also for patients on wheelchairs.                                                                                                                                                                                                             |
| Treatment of spasticity                | Applicable also on spastic fingers ( $MAS \leq 3$ ).                                                                                                                                                                                                                                                                                             |
| Treatment of visuospatial deficits     | The software stimuli can be focused in a specific area/side of the screen in which the patient is asked to concentrate his efforts: this customizable parameter is very useful to treat patients affected by Neglect or other visuospatial disorders.                                                                                            |
| Reports                                | The clinical specialist can supervise the patient's trend and results looking at intuitive charts. The software creates PDF and XLS files for each patient, including all the parameters, data and outcomes of all the performed sessions. These files can be downloaded to the destination chosen by the customer (e.g. hospital server).       |
| Remote assistance                      | Supplier's technicians can do a general check of the device and its main components (e.g. sensors, actuators, electronic board) by remote through SupRemo ( <sup>®</sup> Nanosystems). Also software and firmware updating can be managed by remote.                                                                                             |



## Clinical Indications and Benefits:

Sinfonia Plus is suitable for neurologic patients with motor and/or cognitive deficits. It can be effectively applied in sub-acute as well as in chronic phase to support distal, proximal, functional and cognitive recovery. The most frequent indications are: Stroke, Traumatic Brain Injury, Spinal Cord Injury, Cerebral Palsy, Parkinson's Disease, Peripheral Neuropathies, Neurodevelopmental Disorders. Sinfonia Plus can also be useful supports in the treatment of patients with musculoskeletal disorders and in the post-operative stage.

Sinfonia Plus can help to get the following benefits:

- ▶ Maintenance and improvement of the joint range
- ▶ Proprioceptive stimulation
- ▶ Improvement of visual-spatial and attentive skills
- ▶ Increase in functional independence
- ▶ Reduction of pain, oedema and hypertonia
- ▶ Prevention of adhesions, contractures, and immobilization damages
- ▶ Improvement of joint metabolism, lymphatic and blood circulation
- ▶ Maintenance of functional skills and body perception
- ▶ Increase in coordination and dexterity
- ▶ Increase in grip and pinch strength

## Components:

| SINFONIA PLUS (GSI+) includes: |            |                                     |                                                                                                                                                                                                            |
|--------------------------------|------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                              | GP2        | Gloreha Professional 2              | Motor unit (Dimensions: 53 x 44 x 105 cm; Weight: 25 kg; Working voltage: 24V; Working current: max 6,5A)                                                                                                  |
| 1                              | GAP        | Gloreha Active Package              | Smart unit including 1 Gloreha Sensor Glove Set (GSGZSET_H: 1 unit for each size/side; total: 10 units); 1 Totem for storing up Gloreha Sensor Gloves (GSTOTEM); 1 Electronic Wiring Kit for GAP (ASS0038) |
| 1                              | GMC        | Gloreha Motion Capture              | Sensor Unit (Leap Motion® technology)                                                                                                                                                                      |
| 1                              | GAOZZ23_99 | All-In-One PC                       | Including Gloreha Software – License for Passive Mobilization; Bilateral Training; Therapist-driven Mobilization; Active-Assisted Mobilization; Hand Games                                                 |
| 1                              | GTAZZC+_WH | Height Adjustable Gloreha Table     | C-shaped; 160x90cm; 2 lifting columns (58-103 cm); colour of the table top: white                                                                                                                          |
| 2                              | DAS        | Gloreha DAS                         | 2 Dynamic Arm Supports (12 force levels: 900-4800 grams): 1 left + 1 right                                                                                                                                 |
| 1                              | GBGZSET_H  | Gloreha Silicone Brace+Glove Set    | 1 unit for each size/side of Gloreha Silicone Brace+Glove; total: 12 units                                                                                                                                 |
| 1                              | GHFZSET    | Gloreha Silicone Finger Set         | 1 unit for each size of Gloreha Silicone Finger; total: 18 units                                                                                                                                           |
| 1                              | GHFTSET    | Gloreha Silicone Finger+Thimble Set | 1 unit for each size of Gloreha Silicone Finger+Thimble; total: 18 units                                                                                                                                   |
| 2                              | GSP        | Gloreha Splint                      | 2 accessories for wrist stabilization: 1 small size + 1 large size                                                                                                                                         |
| 1                              | GLO0SET_H  | Gloreha Silicone Loop Set           | Accessory for spastic fingers                                                                                                                                                                              |
| 1                              | CASGWSW    | Chest of drawers                    | Useful to store up gloves and accessories                                                                                                                                                                  |

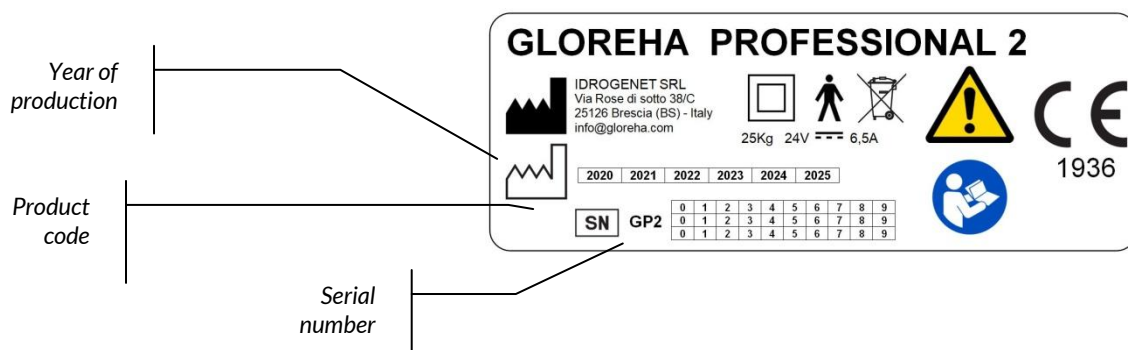
## Technical Data:

SINFONIA PLUS is the commercial brand that includes the medical devices called “Gloreha Professional 2” (GP2) and “Gloreha Active Package” (GAP) and “Gloreha Aria” (GAR) and other items aimed at optimizing the clinical application.

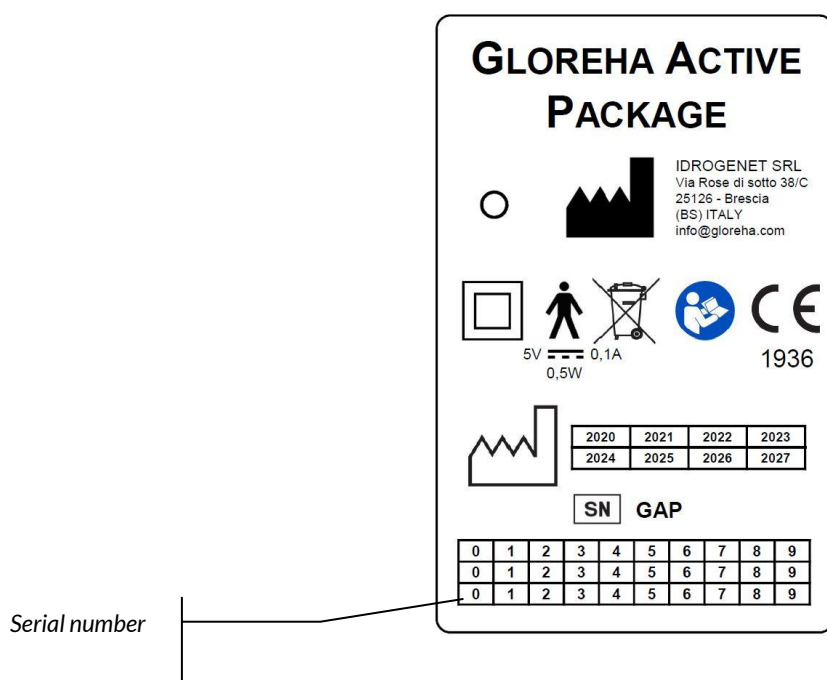
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| Manufacturer                                                                            | Idrogenet Srl -Headquarters: Via Monsuello 246, 25065 Lumezzane (BS), Italy<br>Registered Office: Via Rose di Sotto 38/C, 25126 Brescia, Italy                                                                                                                           |
| Medical Devices                                                                         | Gloreha Professional 2 (GP2)<br>Gloreha Active Package (GAP)<br>Gloreha Aria (GAR)                                                                                                                                                                                       |
| Classification according to Directive 93/42/CEE                                         | GP2-GAP: IIa<br>GAR: I                                                                                                                                                                                                                                                   |
| CE Mark                                                                                 | GP2-GAP: According to the Directive 93/42/CEE – Certificate No. ED 60147365, dated 25th March, 2020<br>GAR: according to the Medical Device Regulation (EU) 2017/745                                                                                                     |
| GMDN code                                                                               | GP2-GAP: 47517 (“Virtual-display rehabilitation system, powered-support”)<br>GAR:48147 (“Virtual-display rehabilitation system, passive-support”)                                                                                                                        |
| CND code                                                                                | GP2-GAP: Z120616 (“Physical Therapy and Rehabilitation Systems”)<br>GAR: Z12069099 (“Various physiotherapy and rehabilitation instruments – Others”)                                                                                                                     |
| Number of registration on Medical Devices Italian Directory                             | GP2: 1942561 - GAP: 1559903 - GAR: 1697138                                                                                                                                                                                                                               |
| Working voltage                                                                         | GP2: 24V<br>GAP: 5V                                                                                                                                                                                                                                                      |
| Working current                                                                         | max 6,5A                                                                                                                                                                                                                                                                 |
| Degree of protection against ingress of water                                           | Common protection                                                                                                                                                                                                                                                        |
| Protection against electric shock                                                       | II                                                                                                                                                                                                                                                                       |
| Applied part                                                                            | type B                                                                                                                                                                                                                                                                   |
| Software                                                                                | The device can be used if connected to a PC with GSWP2 Software installed                                                                                                                                                                                                |
| Connection requirements                                                                 | type B male/type A male USB communication cable                                                                                                                                                                                                                          |
| Computer minimum requirements                                                           | Operating system: Windows 10<br>RAM: DDR4 8GB<br>CPU: Intel i5 2,4 GHz<br>Dedicated graphics card: Nvidia 2GB<br>Memory and available space: SSD 512GB<br>Screen resolution: 1920x1080<br>Display: 23” Full HD<br>Enabled audio output (integrated or external speakers) |
| Conditions of operations                                                                | Ambient temperature from +10°C to +40°C (50° to 104°F); humidity from 30% to 75% relative, 90% with no condensation; atmospheric pressure from 700 hPa to 1060 hPa                                                                                                       |
| Conditions of transport and storage                                                     | Ambient temperature from -10°C to +50°C (14° to 122°F); humidity from 5% to 85% with no condensation                                                                                                                                                                     |
| Polarity of power plug                                                                  | pin 1 and pin 2 positive polarity; pin 3 and pin 4 negative polarity                                                                                                                                                                                                     |
| Medical power supply unit                                                               | Output power 150 W; output voltage: 24.0 VDC; output current: 6.25 A                                                                                                                                                                                                     |
| Noise                                                                                   | 60 dB                                                                                                                                                                                                                                                                    |
| Chassis auto-extinguishing level                                                        | V0                                                                                                                                                                                                                                                                       |
| Equipment for continuous operation                                                      |                                                                                                                                                                                                                                                                          |
| Equipment not suitable for use in an environment rich in a flammable anesthetic mixture |                                                                                                                                                                                                                                                                          |
| Patents                                                                                 | Europe: no. EP2549971 ; USA: no. 9,375,382 B2; China: no. ZL201180015095.9;<br>Japan: no. 5871898; Canada: no. 2,794,193; India: no. 382679                                                                                                                              |
| TARIC/HS code                                                                           | 9019109.000                                                                                                                                                                                                                                                              |

## Labels:

The serial number identifier of GP2 is legible on the plate on the bottom rear of GP2.



The serial number identifier of GAP is legible on the plate on the bottom area of the electronic board.



The plate with serial number of GAR is placed on its original box.

