GIVAS
health human comfort

AP1160 - AP1164

Blood donor armchair

CE

Instructions for installation and use

Istruzioni originali

EN

Thanks for choosing GIVAS SRL!

"GIVAS SRL" is committed to continuously improve its products and its service for a full customer satisfaction.
Our service centres are at your disposal whatever installation, use or maintenance needs you may have.
We firmly believe that every person or organization that chooses one of our products contributes to enhancing our work and we can only thank you by continuing to work to deserve your trust and to always guarantee you the best of our intentions, actions and products.
In order to achieve the objectives described above, we ask you to take few minutes to fill in and send us the questionnaire that you can find on the website **www.givas.it** in the **"Rate Us"** section.
Remaining available for further clarification and thanking you for your attention, we take this opportunity to offer you our best regards.

REVISION TABLE		
REVISION	**DATE**	**NOTES**
0.0	20/01/2017	First edition
0.1	27/03/2017	Technical data and accessories update
0.2	12/04/2019	Added chapter "Demolition and disposal", ISO update
1.0	10/11/2020	CE marking according to Regulation 2017/745 and accessories update
1.1	29/01/2021	Replacement roll holder cod. MZ5048 with MZ1048
1.2	23/04/2021	Basic UDI code input
1.3	24/08/2021	Labelling update
1.4	17/12/2021	Update of the declaration of conformity
1.5	14/03/2023	Replacement of IV pole and clamps

Content

1. CERTIFICATIONS

CERTIFICATE

TÜV AUSTRIA

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

of conformity to the standard
UNI EN ISO 9001:2015

Awarded to:

GIVAS S.r.l.
Registered Office:
Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italy

for the implementation of Management System on sites:

Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italy
Via Canada, 11/4 – 35127 Padova (PD) Italy

Scope:
Design, manufacturing, distribution and servicing of medical technical furnishings and accessories for hospitals and other health care facilities. (IAF 17)

FAC-SIMILE

N° certificate registration: Q-0099-03
Valid until: 30/07/2025
Date of Original Registration: 12/08/2003

Management Representative

Certification Body
TÜV AUSTRIA ITALIA - Blu Solutions S.r.l.

Padova, 23/04/2022

The validity of this certificate is subject to surveillance audits (semi-annual/annual) and to complete reassessment of management system every three years.
This document provides information on the status of certification at the date of issue. It is recommended to verify its validity and authenticity in the website www.tuvaustriaitalia.com or by scanning the QR Code below.

TÜV AUSTRIA ITALIA - Blu Solutions S.r.l. Via Enrico Fermi, 23 35136 Padova (PD)

TÜV AUSTRIA
ITALIA

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 084 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA , IAF e ILAC Mutual Recognition Agreements

IAF
Online Verification

041983-21-6

The valid certification is available in the dedicated area of the website www.givas.it

CERTIFICATE

TÜV AUSTRIA

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

of conformity to the standard
UNI CEI EN ISO 13485:2016

Awarded to:

GIVAS S.r.l.
Registered Office:
Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italia

for the implementation of Management System on sites:

Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italia
Via Canada, 11/4 – 35127 Padova (PD) Italia

Scope:

Design, manufacturing, distribution and servicing of medical technical furnishings and accessories for hospitals and other health care facilities. (IAF 17)

FAC-SIMILE

N° certificate registration: D-0099-19

Valid until: 20/04/2025
Date of Original Registration: 20/02/2019

Management Representative

Certification Body:
TÜV AUSTRIA ITALIA - Blu Solutions S.r.l.

Padova, 20/04/2022

The details of possible exclusion of ISO 13485:2016 requirements may be obtained by consulting the Quality Manual of the registered organization. The validity of this certificate is subject to surveillance audits (semi-annual/annual) and to complete reassessment of management system every three years.
This document provides information on the status of certification at the date of issue. It is recommended to verify its validity and authenticity in the website www.tuvaustriaitalia.com or by scanning the QR Code below.

TÜV AUSTRIA ITALIA - Blu Solutions S.r.l. Via Enrico Fermi, 23 35136 Padova (PD)

TÜV AUSTRIA
ITALIA

Online Verification

041986-21-6

The valid certification is available in the dedicated area of the website www.givas.it

Certificate of Conformity to ISO 14001:2015 standard n. A-0099-17

Awarded to

GIVAS S.r.l.

tax code: 01498810280
Registered office:Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italy

for the implementation of Environmental Management System on site:
Viale Veneto, 2 - Frazione Villatora - 35020 Saonara (PD) Italy
Via Canada, 11/4 - 35127 Padova (PD) Italy

Code: 17

Environmental management system complying with ISO 14001:2015 evaluated in accordance with the Accredia RT-09 requirements.

Scope: Design, manufacturing, distribution and servicing of medical technical furnishings and accessories for hospitals and other health care facilities, processes of mechanical working, welding and assembly.

The validity of this certificate is subject to surveillance audits (semi-annual/annual) and to complete reassessment of management system every three years.
This document provides information on the status of certification at the date of issue. It is recommended to verify its validity and authenticity in the website www.tuvaustriaitalia.com or by scanning the QR Code below.
The scope indicated refers to the complex of activities carried out in the various sites.

Date of Original Registration: 04/08/2017
Date of Current Registration: 29/03/2022
Recertification Due Date: 03/08/2023

TÜV AUSTRIA ITALIA

Management Representative

SGA N° 031 D

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA , IAF e ILAC
Mutual Recognition Agreements

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TÜV AUSTRIA ITALIA - Blu Solutions s.r.l.

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Cap. Soc. i.v. EUR 10.00000
R.I. Ancona REA n. 170070
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TÜV ®

The valid certification is available in the dedicated area of the website www.givas.it

2. DECLARATION OF CONFORMITY EU

The manufacturer:

Company: Givas S.r.l.

Address: Viale Veneto, 2 Z.A. - 35020 Villatora di Saonara (PD) - Italy

SRN: IT-MF-000025753

Declares, under its own and exclusive responsibility, that the device(s)

Code	Model	ID BD/RDM	Basic UDI-DI
AP1160	Blood donor armchair	2184199	805253040AP1160Q9
AP1164	Blood donor armchair with indipendent movements	2184201	805253040AP1164QH

Intended purpose: The device is intended to be used exclusively as an armchair in the treatment of a patient.
Usage environment: within welfare and health facilities.
Product to be used by: patients, specialised operators and doctors.
Supervision and responsibility: the chair must be used under a doctor's supervision.
The armchair cannot be used in a potentially explosive atmosphere.

Risk class: Class I (in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745)

It complies with the following Union legislative acts:

(EU) 2017/745 Regulation (EU) 2017/745 of the european Parliament and of the Council, of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The device is associated with the evaluation procedure provided for by article 52, point 7 of Regulation (EU) 2017/745

Saonara,
December 17, 2021

Chairman of the Board of Directors
Berto Silvio

3. GENERAL RULES

3.1 Purpose of this manual

This manual is an integral part of the article.
Read all warnings and instructions very carefully as they provide important safety precautions and information about the USE and MAINTENANCE OF THE PRODUCT.
Descriptions and illustrations contained in this manual are not binding; “GIVAS SRL” reserves the right to make any modification in order to improve this document without a commitment to updating it.
The illustrations and images used in this manual are example only and may differ in practical application.
In no event shall the manufacturer be liable for any consequential or incidental damages, including any loss of business profits or any other commercial damage that comes from improper use and non-compliance to the instructions described in this manual.

3.2 Customer service

The customer and product assistance services are important parts of “GIVAS SRL” company structure. Customer service is readily available for further information on use, maintenance and service of this product.

3.3 Definitions

The following graphic and linguistic definitions have been used in this manual:

CAUTION! This message may appear before some procedures. Non-compliance may cause damage to the article.

WARNING! This message may appear before some procedures. Non-compliance may cause injury to the operator and to the patient, and may cause damages to the article.

4. SAFETY

4.1 General rules

WARNING! Improper use of the article and improper maintenance can cause damage to people or objects.

WARNING! IN CASE OF BLOOD-TRANSMITTED DISEASES: To reduce the risk of exposure while using the chair, carefully follow the maintenance instructions written in this manual, and the personnel safety regulations as established by the person in charge of the Medical Emergency Service.

Operators must read and follow this manual carefully, and familiarise themselves with the correct operating and maintenance procedures of the armchair.
Always use and carry out the maintenance procedures of the article as prescribed in this manual, and use only “GIVAS SRL” spare parts and “GIVAS SRL” customer service centre.
Do not use the chair for any purpose other than that for which it was intended and designed.
Keep this manual for future reference and to support personnel training. Keep this manual together with the product in the event that you sell or give the product to a new user.
Any major accident which has occurred in relation to the devices shall be reported to the manufacturer and to the competent authority of the Member State in which it is established.

5. INTRODUCTION

5.1 Description

The Blood donor armchair AP1160 and AP1164 are characterized by compact dimensions, complete with four wheels and two fixed front two wheels with rear brake.
Upper part with simple and comfortable design and unique shaped anatomic structure. Backrest, seat and legrest completely padded and upholstered in soft plastic material (skay). The chassis is made of steel painted with epoxy powders, protection casis for backrest/legrest made in thermoformed ABS.
The armchair AP1160 is provided of backrest movement and simultaneous lift of the legrest.
Adjustment is possible through a gas-spring actioned by a bilateral lever.
The article AP1164 is provided of indipendent movements of backrest and legrest. Two bilateral levers allow the adjustment of backrest and legrest.
The armrests, upholstered, are shaped for better containment and adjustable in all directions thanks to a special terminal areas.

5.2 Reference regulations

The item was designed and built by GIVAS S.R.L. in compliance with the general safety and performance requirements set out in Regulation (EU) 2017/745 of 05/04/2017, concerning medical devices.

5.3 Intended purpose

The device is intended to be used exclusively as an armchair in the treatment of a patient.
Usage environment: within welfare and health facilities.
Product to be used by: patients, specialised operators and doctors.
Supervision and responsibility: the chair must be used under a doctor's supervision.
The armchair cannot be used in a potentially explosive atmosphere.

5.4 Environmental limits of use

The environmental conditions of employment of the chair should follow these guidelines:
- temperature: (0, 50 °C);
- Humidity: 10%, 90% (non-condensing).

5.5 Manufacturer

The article described herein is manufactured by:

GIVAS
health human comfort

V.le Veneto, 2 - 35020 SAONARA Z.A.I. - PADOVA ITALY
Tel. +39 049 8790199 - Tel. +39 049 8790710
Fax +39 049 08790711 - E-mail: info@givas.it
www.givas.it

5.6 Life foreseen

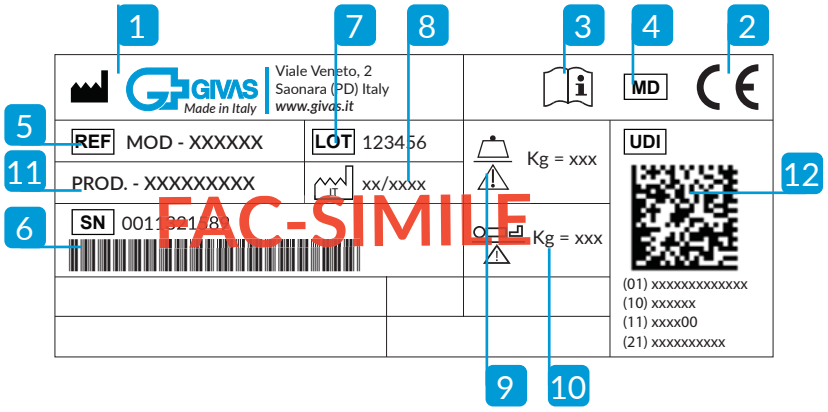
Givas blood donor armchair is designed to operate for 10 years without danger or risk to persons and things within the limits and conditions set forth herein, after which it is recommended to replace the armchair. Proper operation is guaranteed only by contacting our Customer Service Srl GIVAS whenever breakdown of the armchair occurs.

5.7 Markings

CAUTION! The tag on the device must not be removed.

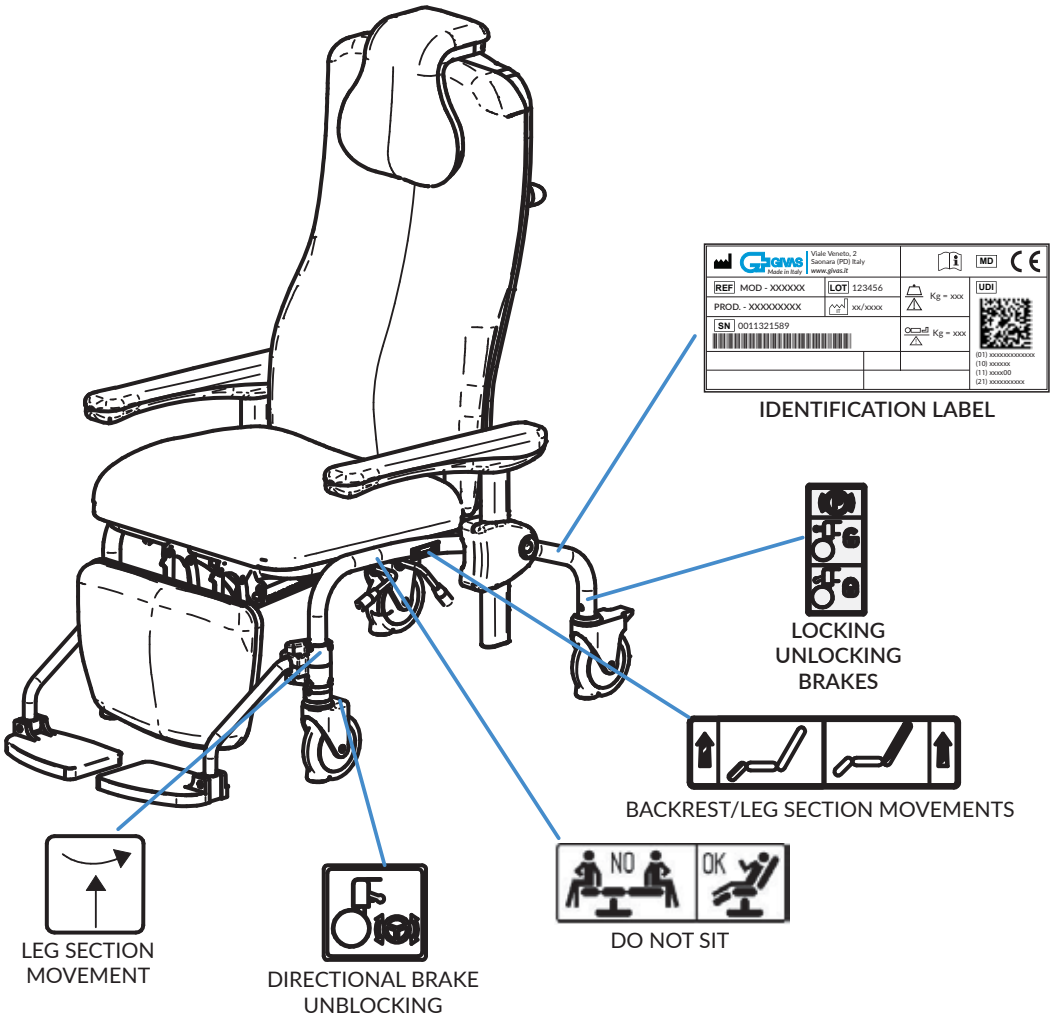
The item can be identified by its rating plate on the base featuring the following data:

1. Name and address of the manufacturer;
2. EEC Marks;
3. Read the instructions for installation and use;
4. Medical Device;
5. Catalogue number;
6. Serial number;
7. Batch number;
8. Date of manufacturing;
9. Safe operating load;
10. Maximum patient weight;
11. Production code;
12. Unique Device Identifier.



5.8 Controls identification

Controls and devices are identified by labels placed near/or on devices themselves.



6. GENERAL DESCRIPTION

6.1 Denomination of the main parts (AP1160)

1. Backrest;
2. Push handle;
3. Armrest;
4. Button height adjustment armrests;
5. Swivel wheels with brake;
6. Simultaneous adjustment lever backrest and legrest;
7. Directional wheels;
8. Legrest;
9. Seat.

6.2 Denomination of the main parts (AP1164)

1. Backrest;
2. Push handle;
3. Armrest;
4. Button height adjustment armrests;
5. Swivel wheels with brake;
6a. Backrest adjustment lever;
6b. Legrest adjustment lever;
7. Directional wheels;
8. Legrest;
9. Seat.

6.3 Technical features

BLOOD DONOR ARMCHAIR		AP1160 / AP1164
Height	mm	1230
Width	mm	720
Length	mm	900 – 1745
Seat width	mm	540
Open chair dimensions	mm	720 x 1745 x 600 h
Closed chair dimensions	mm	720 x 900 x 1230 h
Backrest adjustment	deg	90 – 185
Armrest height from the ground	mm	730
Seat height from the ground	mm	520
Safe operating load	kg	150
Weight	kg	42
Wheels diameters	mm	125

6.4 Material used

All the models are made with a strong steel frame. The backrest is in integral and fireproof polyurethane foam. It contains a metal support frame to keep the shape and provide excellent comfort. Backrest and leg holder are in multi-layer beechwood; the stuffing is made of foam, fireproofing and anatomically shaped (with separate density). The armrests can be lowered or inclined for an easier moving of the patient. They can be either stuffed or made of soft polyurethane.

7. INSTALLATION

7.1 Transport and handling

WARNING! Lifting and handling manoeuvres must be carried out by personnel skilled and trained for this purpose.

Delivery of this product includes an option of: road, railway, sea and air.
The weight of the product is provided through the technical features and from the packaging.
The handling of the single article must be carried out by the suitable equipment: self propelling lift truck, hand lift truck.
Always respect the industrial safety standards.

7.2 Preparing the area of installation

WARNING! The armchair cannot be used in the explosive or flammable atmosphere.

The area of installation must meet the following features:
- rigid, horizontal and level floor;
- lighting 400 LUX.

7.3 Packing list verification

Remove the packaging components and check it against the packing list.
If all the components are present and undamaged, the cardboard box and the rest of packaging can be disposed of or recycled in proper collection areas inaccessible to children and animals.
If the article has been damaged during shipment, keep the cardboard box and the rest of packaging, and call the forwarding agent within 48 hours of delivery.

7.4 Checking the equipment

The packaging includes:
- blood donor armchair AP1160/AP1164;
- any ordered accessories;
- user manual.

7.5 Testing

CAUTION! The following check must be repeated regularly in order to verify the perfect working condition of the item.

Before using the article:
- perform the “periodic review” provided for in Maintenance section;
- if the check is positive, the article is ready for use, otherwise call the “GIVAS SRL” customer service centre immediately.

8. OPERATION AND USE

8.1 Locking wheels

The armchairs are equipped with 4 wheels, two rear braking and two front directional.

To **brake** the wheels:
- press the pedal on the rear wheels with your foot (Fig. 1).

To **unlock** the wheels:
- press the upper part of the pedal located on the rear wheels (Fig. 2).

To set the **directional lock**:
- press the pedal on the front wheels with your foot (Fig. 1).

To return the wheels to the unlocked position, press the top of the pedal.

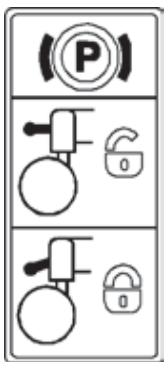
UNLOCK / FREE

LOCK / DIRECTIONAL BLOCK

8.2 How to sit down on the armchair

WARNING! Before seating, lock the wheels when present.

WARNING! Sitting down and getting out of the armchair must be performed in presence of authorized personnel.



In order to sit down on the armchair proceed as follows:
- lock the wheels;
- pull down the armrest;
- sit down on the armchair from one side;
- lift the armrest.

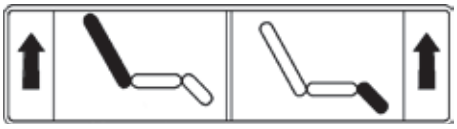
8.3 Getting out from the armchair

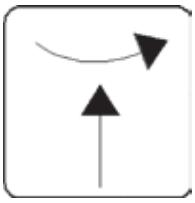
WARNING! Before getting out, lock wheels with the brake.

WARNING! Sitting down and getting out of the armchair must be performed in presence of authorized personnel.

In order to get out of the armchair proceed as follows:
- lock the wheels;
- lift the backrest and pull down the legrest;
- pull down the armrest;
- get out of the armchair from one side.

8.4 Backrest and legrest adjustment (mod. AP1164)





The AP1164 blood donor armchair allow the adjustment of the backrest and leg rest position independently.

WARNING! Do not sit on the backrest when it's horizontally.

WARNING! Do not sit on the legrest when lifted.

WARNING! Backrest adjustment must be performed in presence of qualified personnel.

8.4.1. Backrest adjustment

In order to adjust the inclination of the backrest, proceed in the following way:

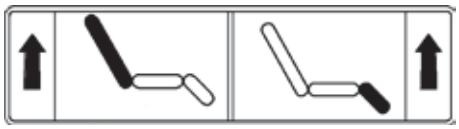
- push the backrest adjustment lever (**6a**) and lower or lift the backrest to the desired position;
- let go of the adjustment lever (**6a**) to block the position.

8.4.2. Legrest adjustment

In order to adjust the tilting of the leg rest, proceed in the following way:

- push the leg rest adjustment lever (**6b**) and lower or lift the leg rest to the desired position;
- let go of the leg rest adjustment lever (**6b**) to block the position.

8.5 Backrest and legrest adjustment (mod. AP1160)



WARNING! Do not sit on the backrest when it's horizontally.

WARNING! Do not sit on the legrest when lifted.

The AP1160 blood donor armchair allow to adjust simultaneously the position of the backrest and of the leg rest using a single lever (**6**).

In order to simultaneously adjust backrest and leg rest, perform the following operations:

- push the lever (**6**) and lower or lift the backrest to the desired position;
- let go of the backrest adjustment lever (**6**) to block the position.

8.6 Armrest adjustment

To **lower** the armrest:
- hold the armrest with one hand and keep the button (**4**) pressed. Pull the armrest downward until the position is blocked.

To **lift** the armrest:
- keep the button (**4**) pressed and use the other hand to hold and lift the armrest. Once the right snagging is reached, release the button.

To **adjust** the height of the armrest, proceed as follows:
- turn the handle (**A**) anti-clockwise;
- either lift or lower the armrest;
- block the position by rotating the handle (**A**) clockwise.

To **tilt** the armrest:
- hold the armrest with one hand and use the other one to turn the handle (**A**) anti-clockwise;
- tilt the armrest until you reach the desired position;
- block the position by rotating the handle (**A**) clockwise.

To **translate** the armrest:
- block the armrest with one hand and use the other one to turn the handle (**B**) anti-clockwise;
- slide the armrest forward or backward until you reach the desired position;
- block the position by rotating the handle (**B**) clockwise.

8.7 Moving the armchair

In order to move the chair, proceed in the following way:

- lift the backrest;
- unblock the wheels;
- push the chair by using the pushing knob which is at the back of the chair (**2**);
- when the chair has been moved, block the wheels.

8.8 Headrest adjustment (Accessory MZ1958 - MZ1059)

The height of the headrest of MR1278 and AP1185 armchairs can be adjusted.
To lift or lower the headrest, pull it either upwards or downwards: a blocking device keeps it into the desired position.

9. DISINFECTION

9.1 Sanitization products

CAUTION! Sanitization agents are corrosive.

Carefully observe the instructions provided by the manufacturer of the sanitization agent during use. Whenever possible, ask the manufacturer for guarantees in regards to the degree of corrosion of the cleaning agents.
It is extremely important to follow the specifications regarding the concentration, temperature and reaction times.
Any modification of these features may damage the item.
In order to sanitize the product use a solution of water and sodium hypochlorite at 1,5%.

9.2 Sanitization intervals

The user defines the sanitization intervals to be adopted, based on their requirements, the information reported in this manual and the instructions listed on the selected sanitization products.

10. MAINTENANCE

10.1 Ordinary maintenance

CAUTION! If there is any sign of damage, disable the article, until the necessary repairs or replacements have been completed.

CAUTION! It is recommended that any technical adjustments, as well as any repairs of the item not specifically listed in this section is carried out by qualified technicians.

The users must control the product at least once a year; the check must see that there is not damage that can compromise integrity and proper operation of the product. I.E.:

- screws properly fixed;
- correct movement functionality, with reference to the section in this manual called “Operating and Use”;
- correct insertion and fixing of accessories;
- wheels and general cleaning of the product (for cleaning instructions see par. “Cleaning”).

10.2 Cleaning

For a better and long life of the article it is essential to carry out periodically a careful general cleaning. We recommend you to proceed as follows:

CAUTION! DO NOT sprinkle directly detergents on to mechanical parts. UNDER NO CIRCUMSTANCES USE solvents, spirit or benzine, detergent or strong abrasive agents to eliminate “hard-to-clean” spots and stains.

If need be or every 15 days:

- clean the metal parts with water and soap, rinse with a damp cloth and dry completely;
- carefully clean the wheels with water and soap, rinse with a damp cloth and dry completely and check their efficiency.

11. DEMOLITION AND DISPOSAL

11.1 Premise

According to current legislation (Legislative Decree no. 152/2006, article 184), waste is divided into three main categories:

- URBAN WASTE: this category includes all waste deriving from human activities such as paper, rags, plastic, cans, bottles, etc.
- SPECIAL WASTE: this category includes all waste deriving from processing in the transformation industry (chemical industry, refineries, tanneries, etc.), craft activities (car repair shops, craft workshops, etc.), agricultural activities (animal breeding, feed mills, etc.) that for quantity and quality cannot be considered similar to urban waste.
- HAZARDOUS WASTE: this category includes all non-domestic waste indicated with an appropriate asterisk in the list called European Waste Catalogue (EWC), in Italy set up by Regulation of Implementation of Commission Decision 2000/532/EC of 3 May 2000.

11.2 Shelving

In case the product needs to be stored for a long period of time, do not forget to:

- place the product in a dry place away from direct sunlight;
- protect it from dust by covering it with a nylon cloth;
- grease the parts which could get oxidised or damaged in case of drying.

11.3 Storage

Long term storage must be performed according to the following conditions:

- the item must be packed;
- the storage area must be dry and not exposed to direct sunlight;
- do not stack up more than 3 item.

11.4 Waste disposal

Disposal of special waste and hazardous waste must be carried out in accordance with the directives in force in the country of use in the field of environmental protection.
In particular, it is advisable to check compliance with the provisions concerning:

- temporary storage of waste (in compliance with the time limits, quantitative limits and technical regulations governed by law);
- completion of loading/unloading registers for those that produce special waste or hazardous waste, in relation to products that can cause such substances due to deterioration, processing or transformation;
- waste transport entrusted exclusively to authorized companies specialized in the specific treatment of the substance;
- destination of waste for recovery and/or disposal (exclusively for parties in compliance with the relative authorizations required by current legislation).

11.5 Demolition

For demolition and scrapping of the item, proceed as follows:

- dismantle and divide the materials that compose it according to their chemical nature (iron, aluminium, bronze, plastic, wood, etc.);
- following the provisions of the law in force in the country where the item is installed, proceed to the scrapping of the various materials and the disposal of the various special and hazardous waste.

12. CERTIFICATE OF WARRANTY

This certificate must be kept until its expiry date.
It must be shown every time technical assistance is deemed necessary, along with the invoice, receipt, delivery note and document containing the name of the dealer who sold the product.
User unable to show the proper documentation will no longer have the rights to the warranty.
The warranty commences from the date of purchase as shown on the invoice, receipt or shipping documents, and is valid for 24 months, concerning the moving and electric parts, for 36 months concerning the structure of the article.
The warranty covers free replacement or repair, within the established terms, of those components that, at the manufacturer's unquestionable judgment, are found to have been defective at origination due to faulty manufacturing.
This warranty does not cover:

- damage due to transportation (scratches, dents and similar);
- damages due to falls;
- damages due to carelessness, negligence, mishandling, incapability of using the equipment, or repairs made by unauthorised personnel;
- damages due to incorrect installation of the equipment, in the event that it is directly installed by the user or by unauthorised personnel;
- damages due to a poor or inadequate electrical system or to changes due to environmental or climactic conditions, as well as damages caused by circumstances of misuse of the equipment;
- technical assistance related to the installation of equipment and its connection to the power supply systems;
- assistance for routine service check-ups or to check for possible defects; ordinary maintenance;
- ordinary wear and tear;
- the replacement of the equipment is in any case excluded.

After-sales service in the warranty period can also be refused in the event that the equipment has been modified or transformed in any way.
The equipment is to be repaired by authorised technicians after the user has made a request to the retailer or directly to the manufacturer, and within time limits compatible with organisational requirements.
In the event of agreed upon assistance, the user will pay the fixed fee for transportation expenses.
If the equipment is repaired at one of authorised Manufacturer's After-Sale Technical Assistance Centres, the user will pay charges and transportation risks.
Repairs made in the warranty period do not imply extensions or renewals of warranty coverage.
The parts replaced during the warranty period remain the Manufacturer's property.
No one can modify warranty terms and conditions or issue other verbal or written warranties.
The Manufacturer declines all responsibility for any damages, whatever their nature, that may directly or indirectly occur to people, animals, or objects in case of improper use of the equipment or if the instructions contained in this manual - mainly those related to equipment installation, use and maintenance - have not been followed.
Moreover, the manufacturer cannot be held responsible for any damages caused to people or objects due to failure or forced halt to the euipment in operation.
Any possible controversy is to be subject to the territorial competence of the court of Padua.

13. ACCESSORIES

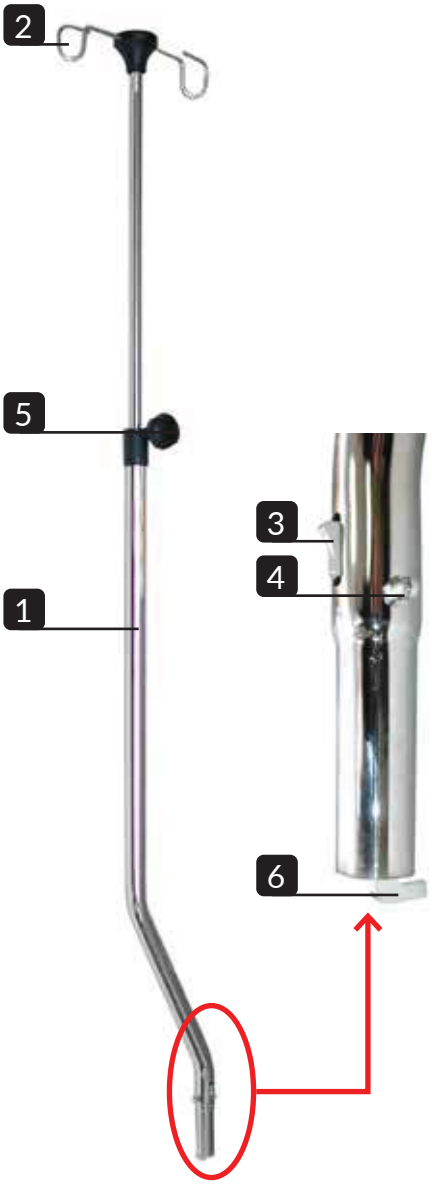
13.1 AP4299 IV pole

13.1.1. Technical description

The IV pole is made of a chrome steel tube at the end of which two shaped chrome steel hooks are welded.

13.1.2. Reference standards

The item was designed and built by GIVAS S.R.L. in compliance with the general safety and performance requirements set out in Regulation (EU) 2017/745 of 05/04/2017, concerning medical devices.



13.1.3. Intended use

The device is intended to be installed on GIVAS armchairs to support IV bags or bottles.
Usage environment: within welfare and health facilities.
The device cannot be used in a potentially explosive atmosphere.
Supervision and responsibility: the device must be used under a doctor's supervision.
People authorised to use the product: specialised operators and doctors.

13.1.4. Materials

The IV pole is made of chrome steel.

13.1.5. Name of the main parts

1. Rod;
2. Shaped hooks;
3. Release hook;
4. Rod positioning pin;
5. Height adjustment knob;
6. Locking hook.

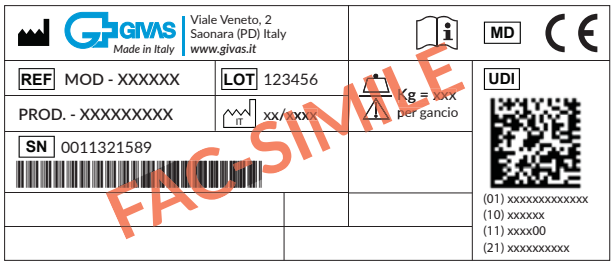
13.1.6. Technical specifications

Size	mm	1200 x 250
Pole diameter	mm	16
Weight	kg	1.5
Safe operating load	kg	3,5 For hook

13.1.7. Identification

CAUTION! The tag on the device must not be removed.

The following label is attached to the item:



13.1.8. Getting ready to install

The IV pole should be installed on GIVAS relax armchair using the fixing clamp MZ5165 (right) or MZ5166 (left) which should be mounted on the armchair by a GIVAS technician. For clamps, ask the GIVAS SRL customer service.

13.1.9. How to install the IV pole

WARNING! Only qualified personnel is authorized to install this item.

Follow the instructions below to install the I.V. stand:

- press the release hook (**3**) and insert the IV pole into the hole (**7**) of the IV pole clamp and push until it engages the rod.

Note: to remove the rod keep the release hook pressed (**3**) and take a tour from the hole pulling upwards.

13.1.10. Functional test

WARNING! The product efficiency check below must be repeated on a regular schedule.

Before placing this item in service:

- check that it works properly referring to the “Operation and use” paragraph of this accessory;
- if the check is positive the item can be placed in service, otherwise get in touch with GIVAS SRL after sales service.

13.1.11. Operation and use

WARNING! Always check that the IV pole is properly installed before use.

WARNING! Do not exceed the safe operating load.

WARNING! There is a residual risk of bumping into the IV pole as it pokes out of the chair.

WARNING! ABOUT BLOOD TRANSMITTED DISEASES: in order to reduce the risk of exposure while using the item, please follow the instructions for maintenance that you can find in this user's manual together with the safety instructions provided by the head of the emergency medical service.

Hang the phlebo by its support to the pole hook (**2**).

13.1.12. I.V. stand height adjustment

To adjust the height of the I.V. stand just grab the rod in the upper part (**1**) with one hand and with the other loosen the adjusting knob (**5**); now adjust the height of the stand and tighten in position with the knob (**5**).

13.2 MZ1048 Roll holder

13.2.1. Technical presentation

Roll holder in chromed steel equipped with sheet holder.

13.2.2. Reference standards

The item was designed and built by GIVAS S.R.L. in compliance with the general safety and performance requirements set out in Regulation (EU) 2017/745 of 05/04/2017, concerning medical devices.

13.2.3. Intended use

The device is intended to be installed on GIVAS armchairs to support the sheet roll.
Usage environment: within welfare and health facilities.
The device cannot be used in a potentially explosive atmosphere.
Supervision and responsibility: the device must be used under a doctor's supervision.
People authorised to use the product: specialised operators and doctors.

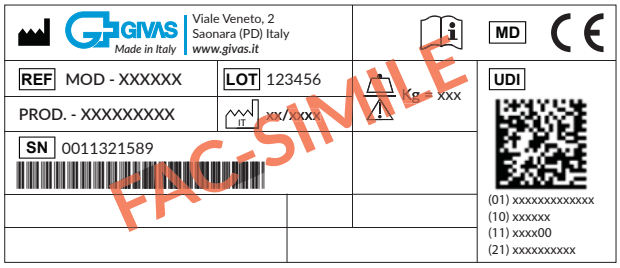
13.2.4. Material used

Chromium-plated wire.

13.2.5. Identification

CAUTION! The tag on the device must not be removed.

The following label is attached to the item:



13.2.6. Name of the components

1. Roll holder support;
2. Pole holding hook;
3. Roll holder pole.

13.2.7. Technical features

Safe work load	kg	5

13.2.8. Installation

The roll holder MZ1048 must be installed on the armchair by a GIVAS technician. For further information, ask the GIVAS SRL customer service.

13.2.9. Cleaning and sanitising

Clean regularly with bactericide action detergents, rinse and dry.

13.2.10. Functional test

WARNING! The product efficiency check below must be repeated on a regular schedule.

Before placing this item in service:

- check that it works properly referring to the “Installation” paragraph of this accessory;
- if the check is positive the item can be placed in service, otherwise get in touch with GIVAS SRL after sales service.

13.2.11. Operation and use

CAUTION! Do not use the roll holder for any other purpose.

WARNING! Always ensure that the roll holder is installed correctly before use.

CAUTION! Unroll the sheet with care, avoiding sudden rips which could take the pole out of its supports.

To change the sheet, take the pole out from the hooks (**2**), pull out the finished roll and replace it, then insert the pole back in the hooks (**2**).

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