

Instructions for use (Manual) and technical description

Infusion stands

**Bed accessories of the company (manufacturer) LINET
Ltd.**

Manufacturer:

MARO-Mader,s.r.o.
Svolinského 218/1A
779 00 Olomouc
Czech Republic



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1. Abbreviations in the text

I.s./i.s. = infusion stand, cat.No. = catalog number.

 WARNING	Read the instructions for use! ❖ Before beginning any manipulation of the i.s. it is necessary to read this manual in detail. All operations and operation of i.s. must be carried out in accordance with it. Any other operations are performed at your own risk and the manufacturer is not liable for any damages! If you perform any other actions on i.s., you do so at your own risk and the manufacturer cannot be held liable for any damages. Keep the instructions carefully until the disposal of the i.s.!
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2. Safety instructions, Conditions of use

Safety instructions

I.s. must not be used if defects have been found which may damage the person being treated, the staff or a third party or the surrounding interior.

I.s. must not be overloaded, even for a short time.

When repairing i.s. only original materials and components can be used. When replacing damaged parts with non-original or unsuitable materials and components, the manufacturer is not liable for any damages.

Before cleaning or maintaining the i.s. mounted on an electric bed, the power cord must always be disconnected from the mains.

I.s. not intended for cleaning in washer.

I.s. must be assembled and installed on the bed in accordance with the procedure given in the operating instructions.

Improper handling of i.s. and its accessories by unauthorized or untrained persons, you can damage the i.s. or its surroundings.

All bed functions can be used together with i.s. The operation of these functions must be under the sole control of a healthcare professional familiar with the instructions for use.

When positioning the bed, take care not to injure the patient or the operator and to collide the i.s. with the bed or its accessories.

Do not use the i.s. to transport the bed.

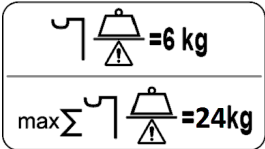
Failure to do so may result in patient injury or the i.s. or the bed damage.

Conditions of use

I.s. is designed for hanging bags (bottles) with infusion solutions and as a supporting structure for the installation of infusion pumps.

Any other use must be consulted with the manufacturer (supplier) in advance.

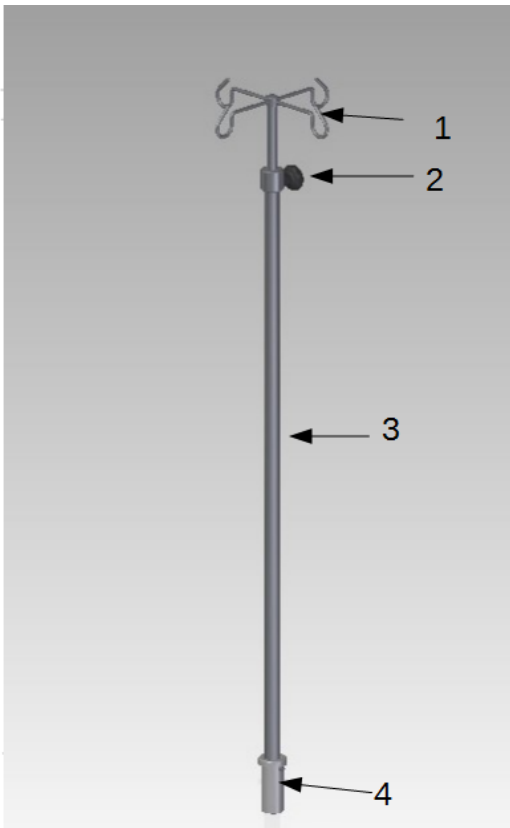
3.Product symbols and labels

	Warning !		Model number
	CE marking of conformity with EU regulations		Serial number
	Label for infusion holder: Load capacity of one hook 6 kgs Load capacity of four hooks 24 kgs		Manufacturer
	Infusion pump installation prohibition label		Date of manufacture
	Medical device		

(product) Label sample



4. Description of the infusion stand variant A, catalog number 250010 for the bed Eleganza 2

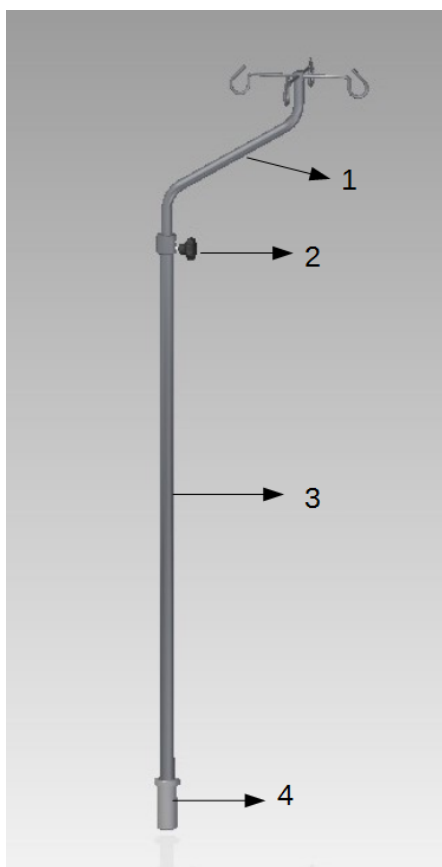


Position	Part identification	Description	Number of pieces
1	D18-L1000	Rod with 4 hooks	1
2	D35-L34	Head with screw locking rosette	1
3	D25-L1000	Outer tube	1
4	D34-L85	Plastic thorn with side pin	1

Assembly:

1. Insert the plastic thorn (pos. 4) into the housing in the bed frame so that the side pin of the plastic thorn fits into the housing cutout in the bed frame.
2. Loosen the screw rosette on the head (pos.2).
3. Slide the rod with 4 hooks (pos. 1) to the desired position and tighten the screw rosette.
4. Check that the rod with 4 hooks (pos. 1) is firmly fixed.
5. If all requirements are met, you can start to use the i.s.

5. Description of the infusion stand variant B, catalog number 250008 for the bed Eleganza 3

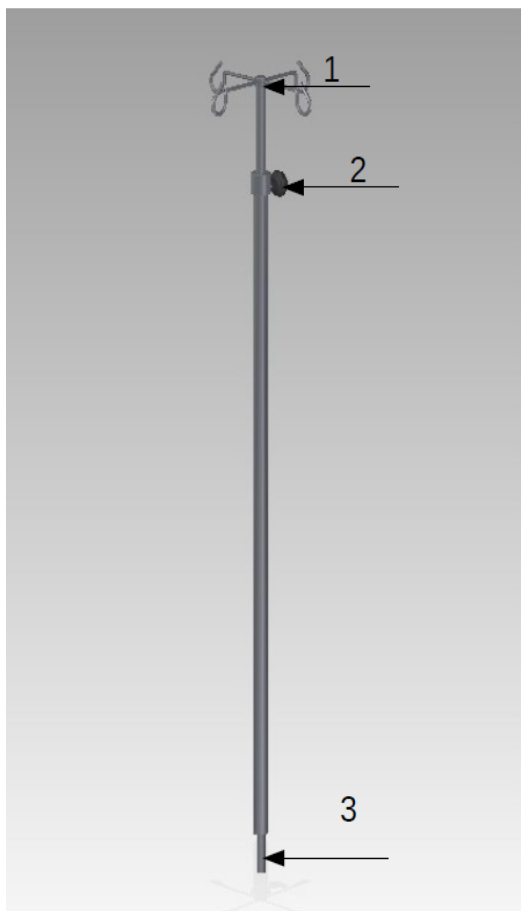


Position	Part identification	Description	Number of pieces
1	D18-L1200	S-shaped rod with 4 hooks	1
2	D35-L34	Head with screw locking rosette	1
3	D25-L1000	Outer tube	1
4	D34-L85	Plastic thorn with side pin	1

Assembly:

1. Insert the plastic thorn (pos. 4) into the housing in the bed frame so that the side pin of the plastic thorn fits into the housing cutout in the bed frame.
2. Loosen the screw rosette on the head (pos.2).
3. Slide the rod with 4 hooks (pos. 1) to the desired position and tighten the screw rosette.
4. Check that the rod with 4 hooks (pos. 1) is firmly fixed.
5. If all requirements are met, you can start to use the i.s.

6.Description of the infusion stand variant C, cat. No. 270001, with thorn 16mm for the bed Multicare MC3

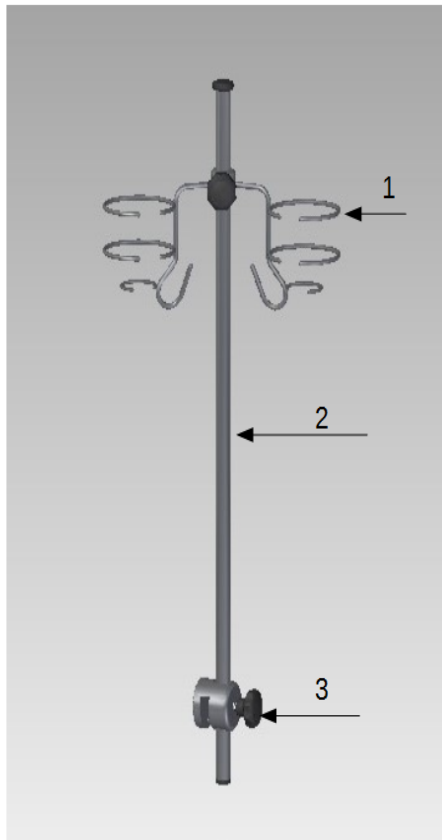


Position	Part identification	Description	Number of pieces
1	D18-L1000	Rod with 4 hooks	1
2	D35-L34	Head with screw locking rosette	1
3	D25/16-L1000	Outer tube with thorn 16mm	1

Assembly:

1. Insert the 16 mm diameter mandrel terminating the outer tube (part 3) into the housing in the bed frame.
2. Loosen the screw rosette on the head (pos.2).
3. Slide the rod with 4 hooks (pos. 1) to the desired position and tighten the screw rosette.
4. Check that the rod with 4 hooks (pos. 1) is firmly fixed.
5. If all requirements are met, you can start to use the i.s.

7.Description of the infusion stand variant D, catalog number 270006, for the bed Eleganza 3XC

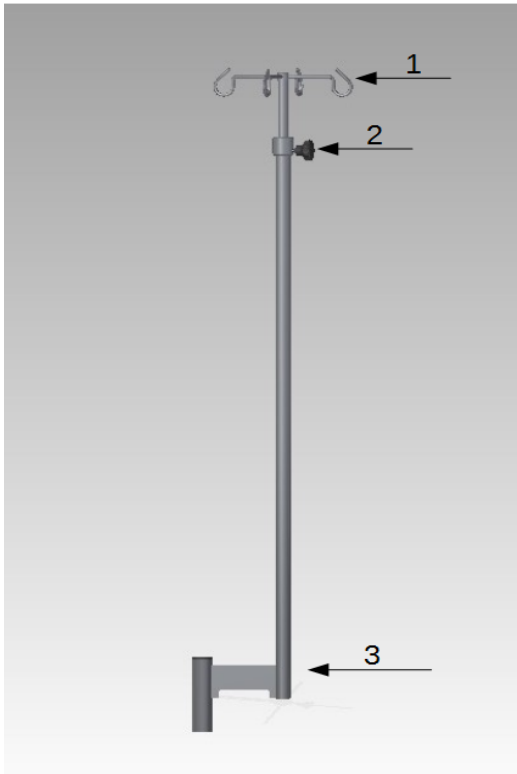


Position	Part identification	Description	Number of pieces
1	2x basket	Heads for baskets	1
2	D18-L800	Rod	1
3	D50-L49	Euro-rail head	1

Assembly:

1. Loosen the screw rosette on the head (part no.3) and attach the head on the Euro-rail.
2. Set the height of the infusion rod (part 2) to the desired value and tighten the screw rosette (part 3).
3. Set the height of the baskets' head (pos1.) to the desired value and tighten the screw rosette.
4. Check that the rod (part 3) and the heads for the baskets (part 1) are firmly fixed.
5. If all requirements are met, you can start using of the i.s.

8. Description of the infusion stand variant E, catalog number 270008, for the bed Eleganza 4

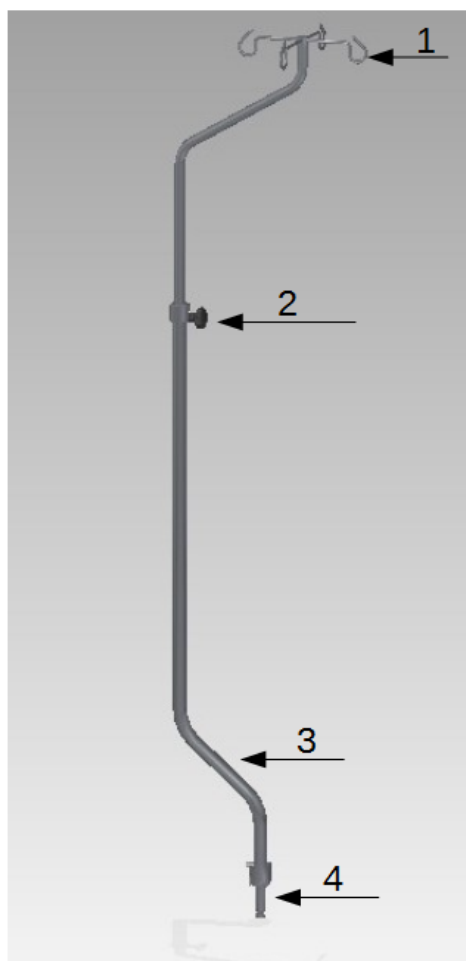


Position	Part identification	Description	Number of pieces
1	D18-L1000	Rod with 4 hooks	1
2	D35-L34	Head with screw locking rosette	1
3	D25/34-110	Outer tube with bracket 110mm and thorn 34mm	1

Assembly:

1. Insert the thorn 34 (pos.3) into the housing in the bed frame so that the lower part of the bracket belt fits into the housing cut-out in the bed frame.
2. Loosen the screw rosette on the head (item 2).
3. Slide the rod with 4 hooks (pos.1) to the desired position and tighten the screw rosette.
4. Check that the rod with 4 hooks (pos.1) is firmly fixed.
5. If all requirements are met, you can start using of the i.s.

9. Description of the infusion stand variant F, cat. No. 270009 for the bed Multicare MC3

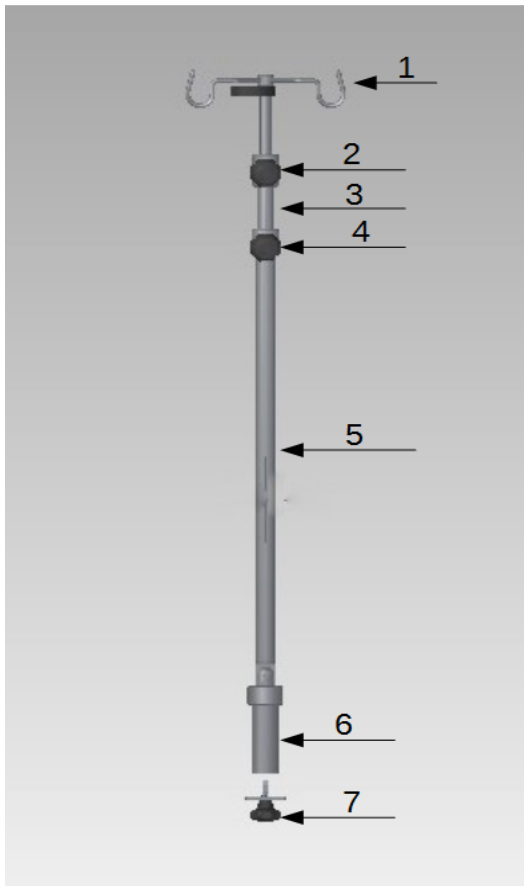


Position	Part identification	Description	Number of pieces
1	D18-L700	S-shaped rod with 4 hooks	1
2	D35-L34	Head with screw locking rosette	1
3	D25-L1056	S-shaped outer tube with thorn 13mm	1
4	D40-L85	Infusion holder adapter	1

Assembly:

1. Insert the infusion holder adapter (pos.4) into the housing in the bed frame.
2. Pull out the outer tube (part 3), rotate to the desired position and fix by fitting the tube pin into the adapter notch (part 4).
3. Loosen the screw rosette of the head (part No. 2), extend the rod with 4 hooks (part 1) to the desired position and tighten the screw rosette
4. Check that the rod with 4 hooks (pos.1) is firmly fixed.
5. If all requirements are met, you can start using of the i.s.

10.Description of the infusion stand variant G, cat.No.270016, foldable, for the bed Eleganza 5

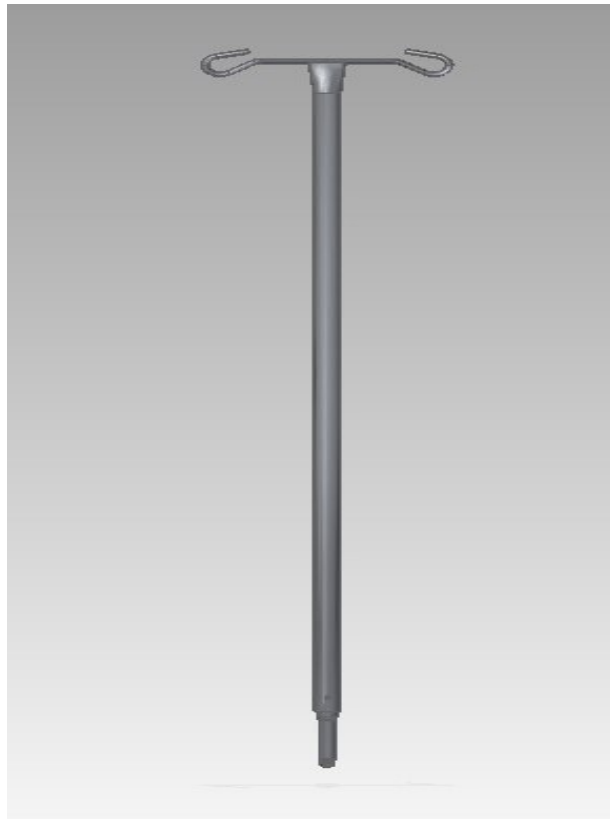


Position	Part identification	Description	Number of pieces
1	16-600	Rod with 2 hooks and a clip for transport	1
2		Head 16/20 with screw locking rosette	1
3	20-600	Middle tube	1
4		Head 20/25 with screw locking rosette	1
5	25-600	Outer tube	1
6	34-117	Thorn with screw rosette joint and washer	1
7		Screw rosette with washer	1

Assembly:

1. Insert the thorn (part no. 6) into the housing in the bed frame and rotate so that the folded i.s. fits with a fastener for transport to the bed frame rail.
2. Fasten the thorn (part 6) in the bed frame housing with a screw rosette with a washer (part 7).
3. Turn the tube (part 5) to a vertical position and insert it into the lower position in the thorn cavity (part No. 6).
4. Fix the lower position with a screw rosette on the side of the thorn (part 6).
5. Loosen the screw rosettes on the heads (parts 2 and 4), extend the rod with 2 hooks to the desired position and tighten the screw rosettes.
6. Check that the rod with 2 hooks (pos.1) is firmly fixed.
7. If the above requirements are met, you can start to use the i.s.
8. Adjust the i.s. to the folded position after releasing the screw rosettes (parts 2 and 4). Then insert the rod with hooks (part 1) and the middle tube (part 3) into the outer tube (part 5).
9. Release the screw rosette on the side of the housing (part 6), extend the outer tube (part 5) upwards and fold it into the transport position so that the transport clip fits the cut-out onto the bed frame.

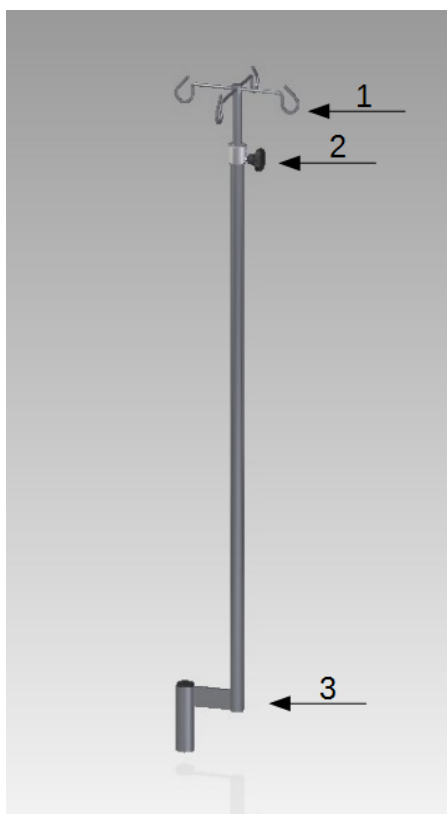
11. Description of the infusion stand variant H, catalog number 270017, for the bed Sprint



The Sprint infusion stand consists of a 1 m long bar with a diameter of 25 mm, topped with two infusion hooks at the upper end, a thorn at the lower end for embedding in the housing in the Sprint bed frame.

ATTENTION! It is forbidden to use the infusion stand as a handling handle to move the bed.

12.Description of the infusion stand variant K, catalog number 270019, for the bed TOM



Position	Part identification	Description	Number of pieces
1	D18-L1000	Rod with 4 hooks	1
2	D35-L34 dural	Head with screw locking rosette	1
3	D25/34-70	Outer tube with bracket 70mm and thorn 34mm	1

Assembly:

1. Insert the thorn 34 (pos.3) into the housing in the bed frame so that the lower part of the bracket belt fits the cut-out of the housing in the bed frame.
2. Loosen the screw rosette on the head (item 2).
3. Slide the rod with 4 hooks (pos.1) to the desired position and tighten the screw rosette.
4. Check that the rod with 4 hooks (pos.1) is firmly fixed.
5. If all requirements are met, you can start using of the i.s.

13.Environmental conditions

Storage/transport conditions:

Temperature: -40 to 70°C / -40 to 160°F Relative humidity: up to 90%

Working/operating conditions:

Room temperature: 10 to 40°C/ 50 to 105°F Relative humidity: up to 80%.

14.Cleaning and disinfection

Use a disinfectant (PROPANOL / ISOPROPANOL or ALDEHYDE-based solution).

Spray disinfectant on surfaces (plastic or metal components).

We recommend paying increased attention to folds, joints, screws.

To ensure optimal cleanliness, it is recommended that you clean the i.s. with each new patient.

15.Warranty and service

The warranty is limited only to the replacement or repair of damaged parts.

The manufacturer guarantees a warranty period of 2 years for defects in i.s. caused by its production (the warranty is valid from the date of purchase of i.s. by customer).

The manufacturer and Linet are the only organizations that is able to assess whether a defective product can be warranted.

Any other use of i.s. that is contrary to the instructions for use will be considered a breach of warranty.

The warranty will also be cancelled due to negligence, insufficient supervision of the patient, insufficient maintenance, unauthorized modification of the i.s. or attempt to repair the i.s.

The warranty covers only defects on the i.s. caused by poor quality of materials used, production and assembly.

The warranty does not cover defects in the i.s. caused by other use of the product than stated in the manual or other unusual use.

Warranty and post-warranty repairs are carried out by the manufacturer or authorized service organizations on the basis of a written certificate of competence to perform these activities.

The relevant certificate shall be issued by the manufacturer.

16.Environmental protection

- The product is constructed of environmentally friendly materials!
- The product does not contain hazardous substances based on cadmium, mercury, asbestos, PCBs (polychlorinated biphenyls) or CFCs (Chlorofluorocarbons)!
All waste packaging arising after the product is put into operation is labelled in accordance with the applicable packaging regulations.
- After installing the beds, the service company sorts all packaging waste according to the graphic symbols and disposes it through an authorized waste management company.
- Contact a sales representative or service technician for the possibility of free take-back of packaging through an authorized waste management company.
- Sort the packaging waste generated during the product putting into operation according to the graphic symbols and hand it over to the authorized person for further use.
- Contains recyclable steel and plastic components – for optimal recycling at the time of product closure, separate the individual parts so that the raw materials from which the product was made can be further used (see Symbols below).



17.Verification of proper installation and frequency of maintenance:

1. Verify that the i.s. is assembled in compliance with the instructions specified in the article ASSEMBLY.
2. The i.s. has no calibrated parameters.
3. Maintenance consists in regular checking of the fixation of the pull-out rod and tightening of the screw rosettes at least 1 time per week, or always when starting to use the i.s. for a new patient.

18. Post-production information to manufacturer from the product use in clinical practice

Inform the manufacturer at the contacts listed below about all user experience, about which he should know.

These are mainly

- defects, deficiencies in the product which have occurred during its use in relation to its function, purpose of use, safety, risks, etc.
- adverse events, suspected ones caused by the product to the patient or operator.

The manufacturer will check everything and will, if necessary, respond. Informs the patient, operator / user about the reaction.

Persons who have experienced an adverse event or suspected one in connection with the use of the product, the manufacturer requests the necessary cooperation in its investigation, or solution, provision of sufficient and accurate information, or image documentation (slides), etc. It will deal with these matters in accordance with its obligations under the regulations in force at the time of their reporting.

Manufacturer contacts:

Website:

www.marocz.eu

Address:

Svolinského 218/1a, 779 00 Olomouc, Czech Republic

Email:

maro@marocz.eu

Phone, Mon-Fri ca. 7am-4pm

+420 585 355 037

SMS, emergency calls:

+420 775 727 656, +420 723 774 035

19.EU declaration of conformity

EU DECLARATION OF CONFORMITY

Pursuant to Article 19 and Annex IV of Regulation No 745/2017 of the European Parliament and of the Council (MDR).
Date of issue: 5/2021

The declaration of conformity is issued by:

BUSINESS NAME	MARO-Mader,s.r.o.
Address	Svolinského 218/1A, Olomouc 779 00, Czech Republic
Organization's ID	01718371
Phone	+420 585 355 037
E-mail	maro@marocz.eu

As a product manufacturer - name
(trademark/tradename):

Infusion stand A,B,C,D,E,F,G,H,K

Product code, catalogue number:	A to K: 250-010, 008, 270-001, 006, 008, 009, 016, 017, 019
Description and determination of the product function:	Infusion stand for use in standard and/or intensive hospital care, for hanging infusion capsules and as a supporting structure for the installation of infusion pumps.
Product classification as a medical device:	Class I non-sterile, without measuring function
Basic UDI-DI/GMN according to Annex VI / C:	859420134IS25-277J
GMDN (generic group) code:	Intravenous pole/36069

Variants **A,B,C,D,E,F,G,H,K**:



A) Declaration

I declare that the product is safe, effective and suitable for the provision of health care under normal conditions of use in accordance with the operating instructions, and that measures have been taken to ensure that all products placed on the market comply with the technical documentation and the essential requirements of MDR regulation applicable to it referred to in paragraph B.

B) Technical and standard requirements met

The properties of this product meet the technical requirements that apply to it, which are listed in:

- MDR EU regulation 745/2017, annexes I, II, III
- Czech Act No. 89/2021 Coll., On medical devices (application of MDR in Czech Republic law system)
- Applicable requirements of Czech Government Decree No. 176/2008 Coll., On machinery (EU Directive 2006/42/EC)
- EN ISO standards 14971, 15223-1, EN standard 1041+A1.

Ing. Stanislav Mader
company director



