



CE Declaration of conformity
in accordance with the annex IV of the Regulation 2017/745
relating to medical devices.

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Guarantees and declares, under its sole responsibility, that the "Gripofix set" containing 3 GRIPOBALLS, 1 Gripofix and 5 GRIPOgram, in accordance with Annex VIII of the European Regulation 2017/745, comply with the requirements for Class 1 medical devices.

This declaration is based on the following elements:

Technical documentation

See Annex II, III and IV
See monitoring

Risk management

The Medical Device (GRIPOBALLS) consists of a plastic sphere (PVC). The additive used to soften PVC is used for soft toys and safe medical applications (phthalate free and compliant with DIN EN71-3 "Safety of toys").

And according to European Directive 2002/72 EC its use is permitted in food contact applications.

The M.D. (Gripofix) is a metacarpal bracelet made of a synthetic rubber strap.

- White color - NBR type (FDA)
- Black color - neoprene type
- Transparent - PVC

The accessories of the M.D. (GRIPOgram) are made of stainless steel balls AISI 316L and are intended only for the ballast of the M.D. (GRIPOBALLS).

Each M.D. and M.D. accessories are accompanied by a usage document.

The M.D. meets functional requirements and is not hazardous.

The M.D. accessories GRIPOgram meets functional requirements and its use must be supervised by a person who has read the recommendations and warnings given in the accompanying instructions for use. Never put the GRIPOgram in your mouth, they could easily be swallowed.

UDI-DI

Gripofix set white (01)05430000493024 - black (01)05430000493109 - transparent (01)05430000493147

Valid until May 25, 2025
Brussels, March 29, 2021

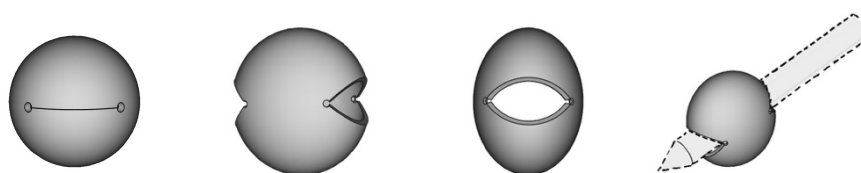
A handwritten signature in blue ink, consisting of several overlapping loops and lines, positioned below the date and location information.

Technical documentation

The device is an aid for gripping small objects, cutlery and conventional writing materials used by everyone in daily life.

The medical device is particularly intended for and provides effective assistance to patients suffering from arthritis, muscle weakness, trauma and/or for people with locomotor problems of the upper limbs (claw and/or hand grip).

The medical device used on, for example, the handle of a pen, due to the enlargement caused, allows such motor handicapped people to grip and better control the grip of the pen. But also for the handles of cutlery (forks, spoons and other knives), which will allow such motor handicapped people or other patients to do without the purchase of special cutlery. The medical device will also have the same effect on toothbrushes, nail files and other small utensils.



GRIPOBALLS \varnothing 4 cm. \pm 18 gr.

Mini-GRIPOBALLS \varnothing 3 cm. \pm 10 gr.

GRIPOBALLS and MINI-GRIPOBALLS are manufactured by rotational molding in the DALYPLASTIC factory located Z.I. Les Manteaux - BP5 89330 Saint Julien du Sault - France.

They are produced in phthalate-free PVC to reduce the risk of allergy as much as possible and to facilitate cleaning and disinfection.

They are then sent to our headquarters where they are finished (cutting), tested, packed and shipped to the customers.

Annex III contains a clinical study entitled "Impact of the use of a grasping aid on the kinematics and functional motor capacities of the hand in healthy subjects".

This study demonstrates the impact of the GRIPOBALLS on kinematics and functional motor skills of the hand and provides evidence that the device does not interfere with daily activities such as writing or eating.

The GRIPOGRAM and MINI-GRIPOGRAM are accessories for the MD. GRIPOBALLS and MINI-GRIPOBALLS

Weighting the GRIPOBALLS or Mini-GRIPOBALLS with AISI 316L stainless steel balls (GRIPOGRAM or mini-GRIPOGRAM) helps to reduce the tremors that interfere with dexterity in some conditions. Pathologies such as dyspraxia, osteoarthritis, polyarthritis, multiple sclerosis, hemiplegia, incomplete tetraplegia, stroke sequelae, Parkinson's, Guillain Barré and all kinds of grip and dexterity deficits.

To insert the ballast, a simple pressure on the sides with the fingers (a small embossed marking on the GRIPOBALLS indicates the place of pressure) allows to widen the opening to insert the Gripogram.

The tool is inserted after the ballast balls have been inserted.

Assistance may sometimes be required to insert the ballast or tool into the Gripoballs, as well as to remove it.

GRIPOGRAM Ø 13,5 mm. – 10 gr.

Mini-GRIPOGRAM Ø 10 mm. – 5 gr.



GRIPOGRAMS are produced in the Marteau Lemarié factory - 3 rue de l'Artisanat - ZI du Moulin du Gillier - 42290 SORBIERS - France.

AISI 316L stainless steel has been chosen for its particular resistance to acids and corrosion to prevent any risk of contamination in case of accidental ingestion.

The stainless steel balls are then sent to our headquarters to be packed with their instructions for use and placed in the packaging of the various MDs.

You can also combine the Gripoballs with the GripoFix to ensure a steady grip or to fill the palm hollow, making it easier to start gripping.

One of the disadvantages of the known fastening devices is that they are difficult to handle with one hand, which does not allow easy use of these devices to wedge or fasten objects against a part of the human body such as a forearm or a hand. In particular, it is difficult for people with gripping difficulties, such as the disabled, the maimed, or those suffering from certain pathologies such as rheumatic deformity, to handle such fastening devices

There is therefore a need for fastening devices that can be easily handled with one hand both for their positioning and for their closing or opening, and which are suitable for use in attaching objects to each other or to a part of the user's body.

The GripoFix aims to solve at least one of the problems encountered in the prior art by offering a new, more hygienic and more ergonomic fastening device, the closing and opening mechanism of which does not require certain elements to be turned in relation to others or to be lifted in order to be inserted, so that the elements involved in the closing process can be handled with one hand.

For this purpose the system has as its object an attachment device for attaching objects to a part of the human body.

According to particular embodiments, it may comprise any of the following features, taken alone or in any combination:

- The head of the clasp has an ovoid, semi-circular or semi-losange shape and the foot has at least one notch at its connection with the head for hooking the edge of the opening when the head is inserted into said opening for closing the fastening device.
- Each end of the device has at least one clasp and at least one opening, said opening being intended to receive the clasp of the opposite end for closing the fastening device.
- The foot connects the clasp to one end of the device body.
- The length of the head of at least one clasp is greater than the length of the foot of the same clasp(s) depending on the length of the body of the device.
- At least one end of at least one clasp-forming notch has a circular, ovoid or elliptical perforation so as to form at least one of the edges of the foot of said clasp and the associated notch or notches.
- At least one end has at least two clasps aligned along the length of the device, preferably with at least one opening interposed between said clasps.
- The clasp(s) are oriented such that the foot of the clasp(s) are parallel to the longitudinal direction of the device.
- The clasp(s) are oriented so that the foot of the clasp(s) is closer to the ends of the device than the top of the head.
- The width of the openings for the clasp(s) is less than or equal to the width of the head of the clasp(s), preferably the width of the openings for the clasp(s) is equal to the width of the head of the clasp(s).
- The part or parts of at least one end comprising either an opening or a clasp have an ovoid or circular shape.
- The opening(s) have a semi-ovoid, semi-circular or semi-losange shape, preferably similar in shape to the shape of the head of the clasp.
- The device also has at least one loop intended to enclose at least one clasp at one end and at least one opening at the other end by sliding along the body, when said clasp or clasps are passed through said opening or openings respectively.
- The apertures are distributed over the ends and the central part of the body, preferably the apertures are evenly distributed over the entire length of the device.
- The device has axial symmetry along a transverse axis and/or along a longitudinal axis.
- The device is symmetrical along its thickness.
- The device is made of an elastic material, preferably an elastomer chosen from a Butadiene-acrylonitrile copolymers (NBR) or a thermoplastic elastomer (TPE) or a synthetic rubber (CR).
- At least one end has at least two clasps aligned along the width of the device.

Said device is a metacarpal bracelet.

It concerns the use of a fastening device as defined above for holding objects against a part of the human body, preferably against a hand.

The metacarpal strap is designed to compensate for a grip where the opposition of the thumb, necessary for the proper holding of a tool, would be deficient.

Only one hand is required to set it up.

The bracelet is placed around the hand and the attachment system is of the buttonhole type.

The hole in the bracelets will allow you to insert the tool to be used (pen, cutlery, toothbrush, power toothbrush, hairbrush, hand shower, badminton racket...).

The advantage of the hole is also to have permanent ventilation in case of intensive use.

Sometimes help may be needed to insert the tool into the hole, as well as to remove it.



White - NBR type (FDA)

Black - neoprene type

Transparent - PVC type

GRIPOFIX - L = 31,5 cm. - W = 4 cm. - T = 2 mm.

GRIPOKID - L = 20 cm. - W = 2,5 cm. - T = 2 mm.

These materials were chosen for the manufacture of GRIPOFIX, GRIPOKID and USYFIX for their physical characteristics such as their resistance to elongation and their shape memory, but also because they can be washed at high temperature and maintain a good hygiene of the device. But also to reduce the risk of allergy as much as possible.

GRIPOFIX are made from NBR sheets (reference B571 from TRELLEBORG), Neoprene CR (ref. CF03 from TRELLEBORG) and transparent soft PVC (Extruflex)

GRIPOKID are made from Neoprene CR sheets (ref. CF03, brand TRELLEBORG)

USYFIX are made from NBR sheets (reference B571 from TRELLEBORG), Neoprene CR (ref. CF03 from TRELLEBORG)

All are cut on a CNC cutting table by Bemden's SPRL factory rue Communale 36 - 1083 BRUSSELS - Belgium.

Annex IV <http://www.sfrm-gemmsor.fr/file/medtool/webmedtool/gemmtool01/botm0034/pdf00013.pdf> contains a clinical study (in French) entitled "Le membre supérieur du tétraplégique, de la compensation à la chirurgie" (The upper limb of the tetraplegic, from compensation to surgery), which demonstrates the value of using a metacarpal wristband such as the GRIPOFIX or GRIPOKID when grasping is not possible due to poor positioning of the fingers or when the injury is too high.