**instructions for use**
**EKG-Patch for long-term ECG monitoring**


**Rev.1**

# General Information / Safety Instructions

The instructions for use must be read carefully before the first start-up and kept for future reference. Non-compliance or improper use releases the manufacturer from liability. Before each use, the medical device and its accessories must be checked for function and intactness. FAROMED GmbH Medizintechnik expressly warns against changing the medical device and its accessories. Any change leads to the exclusion of liability. The CE mark expires with the use of non-approved spare parts. The product may only be used by medically trained personnel!

## Intended use

The EKG patch ZEUS is only intended for attaching the EKG recorder ARES from AthenaDiaX to the patient.

## Note:

Replace the monitoring extension (ECG electrodes) every 24 hours.

## Location, duration, frequency of use

This patch is not reusable and is worn for one, two or up to seven days, depending on the variant.

## Contraindication

See instructions for use body sensor.

## Warnings

Reusing Zeus without permission can lead to cross-infection as cleaning residue or other contaminants may adhere to it. Make sure that the product is intact, damaged devices cannot be used. Protect the device against electrical currents, fields and radiation as well as high temperatures. The battery poses a risk of explosion. Only combinations approved by the manufacturer are allowed. The device can be damaged if an external defibrillator is used.
This EKG patch is not waterproof and must be protected from moisture penetration.

## Handling

Protect the product from mechanical damage! Do not throw! Do not use any force! Apply the patch the right way round. For more information on handling, see the body sensor instructions for use.

## Disposale

After expiration of usage the product needs to dispose in accordance with your local laws, especially the battery. For the European Union is the following directive valid: According to the European directive 2012/19/EU on electrical and electronic equipment (WEEE) is this product not allowed to get disposed in your household waste. Prepare the product and its accessories for recycling or separate collection according to the directive. The directive is only valid for not contaminated products.

## Technical data

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| **biocompatibility of the adhesive film** | DIN EN10993-1; DIN EN10993-10 |
| **distribution** | AthenaDiaX GmbH, Heinrich-Mann-Allee 3b 14473 Potsdam |
| **size** | 57,4 x 57,4 x 10 mm |
| **weight** | Ca. 24 g |
| **batteries** | Lithium-Manganese-Dioxid; 3,0 V; 450 mAh - 700mAh |
| **durability** | 2 years, at a temperature of 21ºC and relative humidity of 50% in the original packaging |
| **classification** | Class I acc. Annex IX, RL 93/42 EWG |
| **Item number** | Zeus 1D: REF 01-102-1D<br>Zeus 2D: REF 01-102-2D<br>Zeus 7D: REF 01-102-7D |

## Symbols and inscriptions

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| CE | **CE labelling**<br>The device complies with the requirements of the European Council Directive 93/42 / EEC for medical devices. |
| | **Information about the manufacturer**<br>Shows the manufacturer of the medical device. |
| | **hazardous waste**<br>Must not be disposed of with normal household waste;<br>Must be disposed of in an environmentally friendly manner in accordance with local regulations. |
| | **do not reuse**<br>Refers to a medical device that is intended for single use or for use on a single patient during a single treatment (e.g. EKG patch). |
| | **Attention - note the accompanying documents!**<br>Refer to the accompanying documents before use and if anything is unclear. |

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| | **Observe the operating instructions**<br>Indicates the need for the user to refer to the instructions for use. |
| LOT | **batch code**<br>Displays the manufacturer's batch designation so that the batch or lot can be identified. |
| REF | **item number**<br>Displays the manufacturer's order number so that the medical device can be identified. |
| SN | **serial number**<br>Displays the manufacturer's serial number so that a specific medical device can be identified. |
| | **application part: Type BF** |
| LATEX | **contains or presence of natural rubber latex**<br>Indicates the presence of natural rubber or dry natural rubber latex as a construction material in the medical device or the packaging of a medical device. |

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| NON STERILE | **unsterile**<br>To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized. |
| % | **Humidity, limitation**<br>Describes the moisture range to which the medical device can be safely exposed. |
| | **temperature limitation**<br>The upper and lower temperature limit values must be indicated next to the upper and lower horizontal lines. |
| | **Keep dry** |
| | **Do not use if the packaging is damaged**<br>Indicates a medical device that should not be used if the packaging is damaged or opened. |

## Support

For questions and problems with the body sensor please contact:

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