

## ROTOFIX 32 A



<b>(EN)</b>	<b>Operating Instructions.....</b>	<b>5</b>
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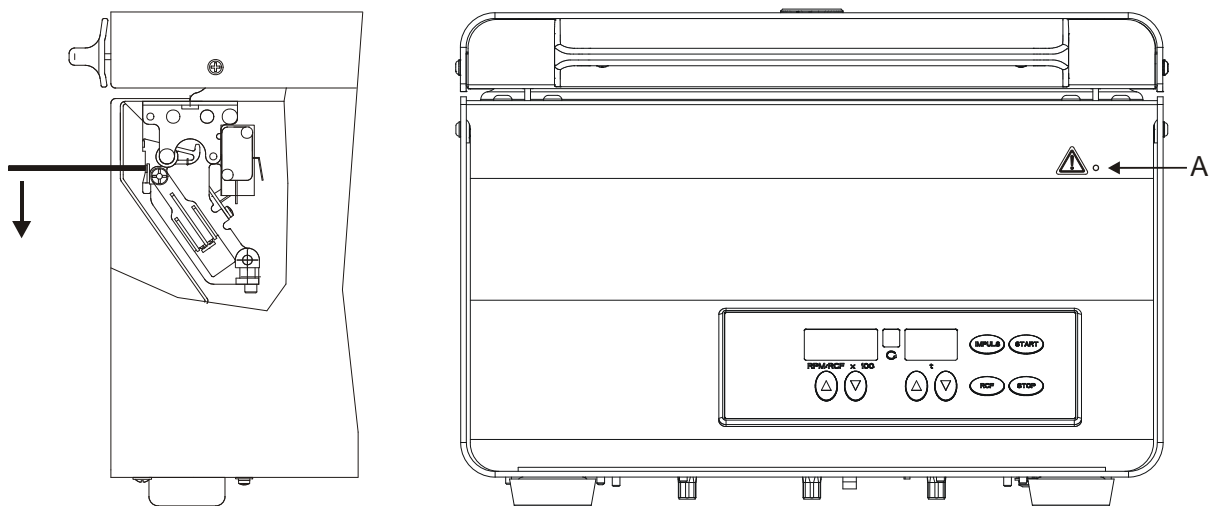


Fig. 1

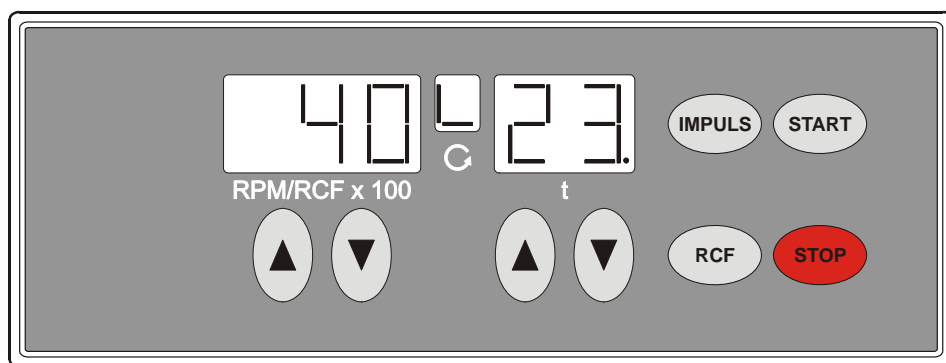


Fig. 2 ROTOFIX 32 A

## Standards and regulations which apply to this device

The device is a high-end technical product. It is subject to extensive testing and certification procedures according to the following standards and regulations in their respectively valid version:

### Electrical and mechanical safety for design and final testing:

Standard series: IEC 61010 (conform to standards of DIN EN 61010)

- IEC 61010-1 "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements" (Pollution Degree 2, Excess-voltage category II)
- IEC 61010-2-010 „Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of Materials" (only valid for centrifuges with heating)
- IEC 61010-2-011 „Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-011: Particular requirements for refrigerating equipment" (only valid for centrifuges with cooling)
- IEC 61010-2-020 "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges"
- IEC 61010-2-101 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"

### Electromagnetic Compatibility:

- EN 61326-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements"

### Risk management:

- DIN EN ISO 14971 "Application of risk management to medical devices"

### Restriction of Hazardous Substances (RoHS II):

- EN 50581 "Technical documentation for assessing electric and electronic devices with regard to the restriction of hazardous substances"

### European directives applied for conformity assessment procedures:

- In vitro diagnostic device directive 98/79/EG  
EC conformity assessment procedure according to annex III "EC DECLARATION OF CONFORMITY" – self-declaration by the manufacturer
- Directive 2011/65/EU for the restriction of use of certain hazardous substances in electric and electronic devices. Carrying out the EC conformity assessment process is the sole responsibility of the manufacturer, without the involvement of a notified body.

### Applied medical device regulations outside Europe:

- **USA:** QSR, 21CFR 820 "CFR Title 21 - Food and Drugs: TITLE 21- FOOD AND DRUGS, CHAPTER I - FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES, SUBCHAPTER H - MEDICAL DEVICES, Part 820 QUALITY SYSTEM REGULATIONS"
- **Canada:** CMDR, SOR/98-282 "Medical Devices Regulations"

### Certified quality management system according to

- ISO 9001 "Quality management systems – Requirements"
- ISO13485 "Medical devices - Quality management systems - Requirements for regulatory purposes"

### Environmental management system according to

- ISO 14001 "Environmental management systems - Requirements with guidance for use"

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