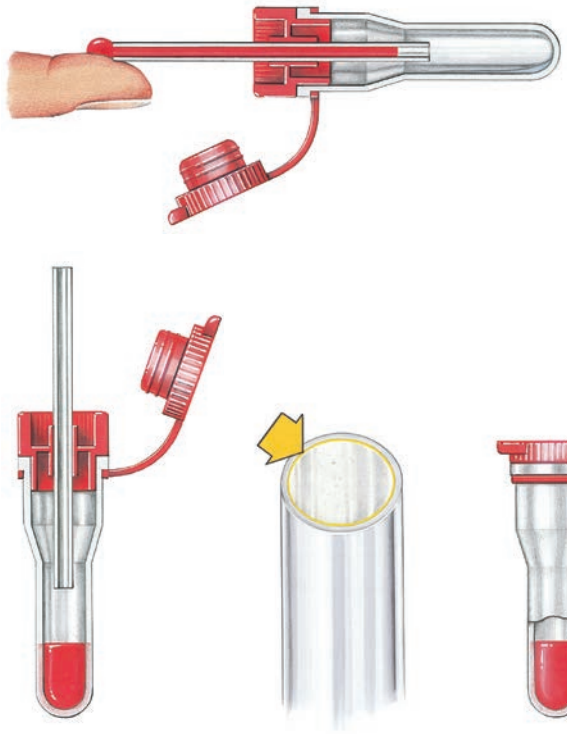
# Capillary blood collection GK

For the capillary blood collection of KABE LABORTECHNIK, which was developed as an addition to the venous blood collection systems, smallest sample quantities are sufficient. The system offers special advantages for the collection of blood samples from babies, children, elderly people and emergency patients, thus everywhere, where only small amounts of blood are available.

The test vessel is prepared on the entire inner surface. Besides it can be used as centrifugal vessel. The dimension of the vessel ensures that by use of commercial pipettes and pipette tips the necessary sample material can be taken without any problems.

The capillary is made of unbreakable plastic, preventing cut and stab injuries. It is coated on the entire inner surface and guarantees an exact filling volume.

The attached stopper, which can be easily opened with one hand, offers perfect tightness. The capillary blood collection GK allows an easy, hygienically flawless handling.

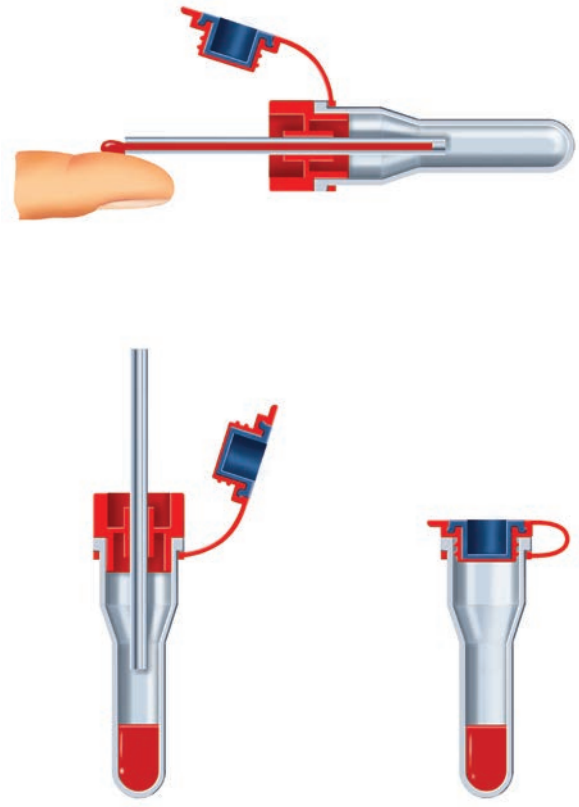


## Capillary blood collection GK with rubber membrane

In addition to the normal capillary blood collection system, it is also possible to obtain the system with an integrated rubber membrane in the attached stopper.

This rubber membrane consists of an elastically re-deforming material and lies on the extremely thin bottom of the sealing cap.

The rubber membrane can be easily pierced from the sampler needle of an analyser. After the needle is removed, the rubber membrane seals completely again and thus ensures absolute tightness of the stopper.



**Advantages:**

- Minimisation of the risk of infection for the user
- Low risk of sample contamination
- No leakage and evaporation of sample after analysis
- Possibility of short-term storage of samples without loss of sample material
- Increased sample use due to multiple use of the sample on the analyser
- Prevention of absorption effects due to thin bottom

TÜVRheinland®

# Certificate

**The Certification Body of**
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**KABE LABORTECHNIK GmbH**
**Jägerhofstr. 17**
**51588 Nümbrecht**
**Deutschland**

has established and applies a quality management system for medical devices for the following scope:

**Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

| | |
|---|---|
| Effective Date: | 2018-10-16 |
| Certificate Registration No.: | SX 60133221 0001 |
| An audit was performed. Report No.: | 21234760 009 |
| This Certificate is valid until: | 2021-10-15 |

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-10-12

Dipl.-Ing. I. Munkler

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60105393 0001

**Report No.:** 21234760 001

**Manufacturer:**
KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

**Products:**
- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces Approval, Registration No.: HD 60034211 0001

**Expiry Date:** 2020-10-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

**Effective Date:** 2015-10-16

**Date:** 2015-10-16

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** HD 60105393 0001
**Report No.:** 21234760 001

**Manufacturer:** KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2015-10-16

Dipl.-Ing. I. Munkler

KABE LABORTECHNIK

# EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

| | |
|---|---|
| Name und Adresse des Herstellers:<br>Name and address of the manufacturer: | **KABE LABORTECHNIK GmbH**<br>**Jägerhofstraße 17**<br>**51588 Nümbrecht-Elsenroth**<br>**Deutschland / Germany** |

Wir erklären in alleiniger Verantwortung, dass die In-Vitro-Diagnostika der Produktgruppe /
We declare under our sole responsibility that the in-vitro-diagnostica of product group

| **kapillare Blutentnahmesysteme** | **capillary blood collection systems** |
|---|---|
| • **Kapillarblutentnahmesystem (GK)**<br>• **kapillare Probenbehältnisse**<br>  • Blutgaskapillaren (BK)<br>  • Hämatokritkapillaren (HK)<br>  • end-to-end Kapillaren (EK) | • **capillary blood collection system (GK)**<br>• **capillary sample containers**<br>  • blood gas capillaries (BK)<br>  • haematocrit capillaries (HK)<br>  • end-to-end capillaries (EK) |

| | |
|---|---|
| der Klasse / of class | **Andere IVD-Produkte**<br>**Other IVD-devices** |

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EEC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

| | |
|---|---|
| Konformitätsbewertungsverfahren:<br>Conformity assessment procedure: | **Richtlinie 98/79/EWG Anhang III**<br>**Directive 98/79/EEC Annex III** |

Nümbrecht-Elsenroth, 21.03.2013

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
D-51588 Nümbrecht-Elsenroth
☎ +49 (0) 2293 / 596

André Kolpe, Geschäftsführer / Managing director

VACUTEST kima

www.vacutestkima.it

# DICHIARAZIONE DI CONFORMITÁ CE
## EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
*according to Annex III of the Directive 98/79/EC on* "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi / disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

**Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.**

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
***devices other then those mentioned in Annex II of the Directive 98/79/EC as amended***

**Si dichiara**

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

***Hereby we declare***

*under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on* "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
**Giovanni Chiarin**

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
*WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY*

# KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

## UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

**EA: 29**

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
*Refer to the documentation of the Quality Management System for details of application to reference standard requirements.*

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
*The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.*

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
*For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.*

| Data emissione | Emissione corrente | Data di scadenza |
|---|---|---|
| *First issue* | *Current issue* | *Expiring date* |
| 18/01/2007 | 18/01/2019 | 17/01/2022 |

**ICIM S.p.A.**
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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ICIM

CERTIFICATO n.
*CERTIFICATE No.* **4265/4/C**

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*WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY*

# KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

## UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

**EA: 29**

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

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|---|---|---|
| *First issue* | *Current issue* | *Expiring date* |
| 18/01/2007 | 18/01/2019 | 17/01/2022 |

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*CISQ is the Italian Federation of management system Certification Bodies.*

0860CM_02_IT

THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/ICIM SPA** has issued an IQNet recognized certificate that the organization:

## KIMA S.r.l.

**Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)**

has implemented and maintains a

Quality Management System

for the following scope:

**Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.**

which fulfils the requirements of the following standard:

## ISO 9001:2015

| | |
|---|---|
| Issued on: | **2019-01-18** |
| First issued on: | **2007-01-18** |
| Expires on: | **2022-01-17** |

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Registration Number: IT-53168

*Alex Stoichitoiu*
*President of IQNET*

*Ing. Claudio Provetti*
*President of CISQ*

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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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## KIMA S.r.l.

**Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)**

has implemented and maintains a

Quality Management System

for the following scope:

**Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.**

which fulfils the requirements of the following standard:

## ISO 13485:2016

| | |
|---|---|
| Issued on: | **2019-01-18** |
| First issued on: | **2007-01-18** |
| Expires on: | **2022-01-17** |

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Registration Number: IT-70247

*Alex Stoichitoiu*
*President of IQNET*

*Ing. Claudio Provetti*
*President of CISQ*

IQNet Partners*:
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CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
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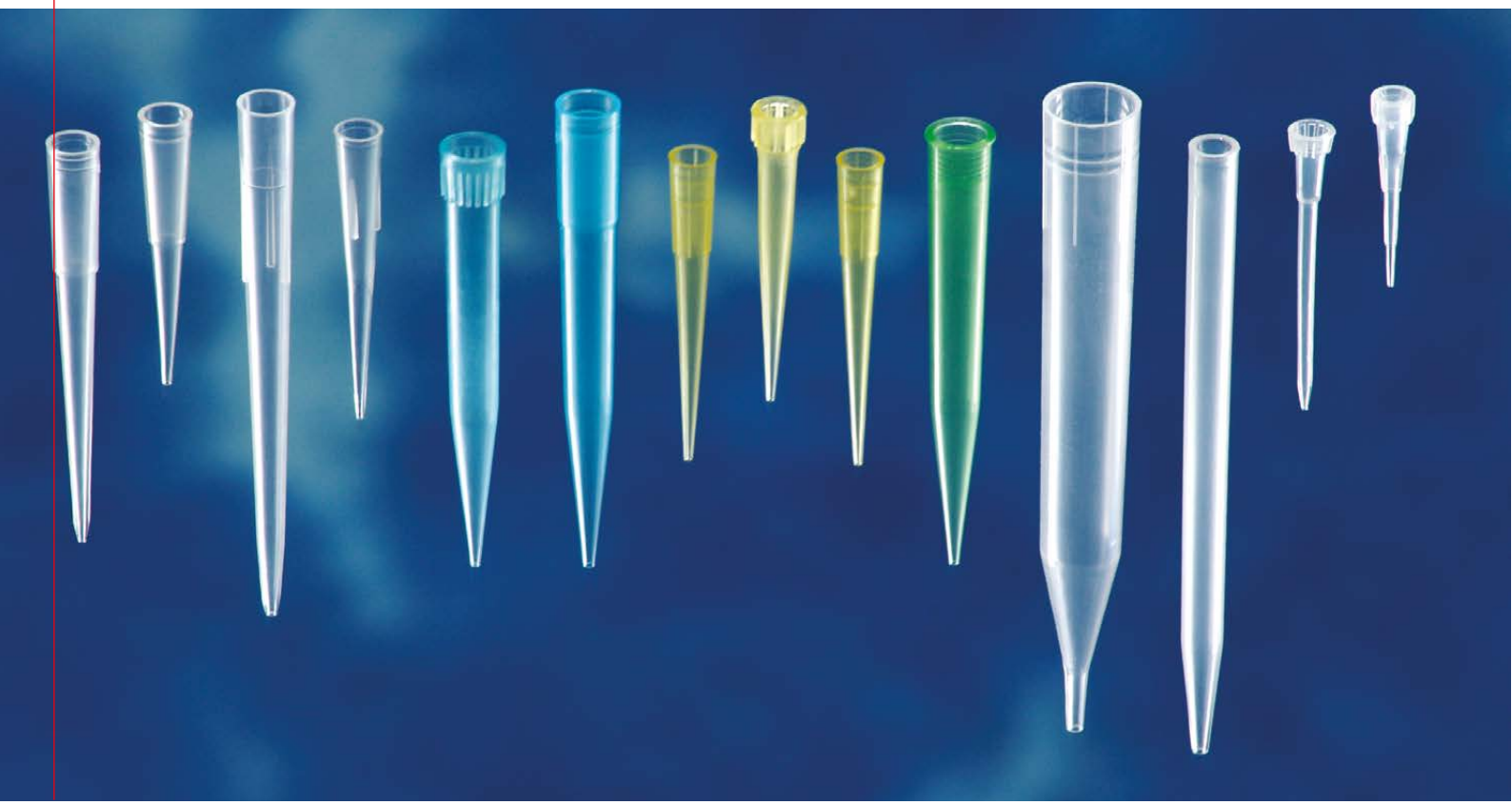
# Puntali

*Tips*



18293
NON STERILE
18294
STERILE

Vol. 0:10 ul.

Puntale bianco per autopipetta tipo Gilson micro.

*White tip for automatic pipette micro Gilson type.*

18291
NON STERILE
18292
STERILE

Vol. 0:10 ul.

Puntale bianco per autopipetta tipo Eppendorf micro.

*White tip for automatic pipette micro Eppendorf type.*

18260
NON STERILE
18261
STERILE

Vol. 0:200 ul.

Puntale giallo per autopipetta tipo Gilson.

*Yellow tip for automatic pipette Gilson type.*

18170
NON STERILE
18171
STERILE

Vol. 0:200 ul.

Puntale giallo per autopipetta tipo Eppendorf-Brand-Socorex.

*Yellow tip for automatic pipette Eppendorf-Brand-Socorex type.*

18172
NON STERILE
18173
STERILE

Vol. 200:1000 ul.

Puntale azzurro per autopipetta tipo Eppendorf-Gilson-Brand-Socorex.

*Light blue tip for automatic pipette Eppendorf-Gilson-Brand-Socorex type.*