

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Germany**

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, final inspection and distribution of disinfectants
Manufacture, final inspection and distribution of medical devices
as par attachment 1
Purchase, packaging, storage and distribution of medical devices**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 01 March 2022

Report No.: QS2239FS19F
Process No.: QS - 2239
Certificate No.: 2239GB445190711

Hamburg, 11 July 2019



MEDCERT Certification Body
(Lorenz Runge)

**DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

Attachment 1
Certificate
QS - 2239

This attachment is valid only in connection with certificate No: 2239GB445190711

- **Blood lancets**
- **Medical electric thermometers**
- **Scalpels and scalpel blades**
- **Vacuum bottles**
- **Nasal oxygen cannulas**
- **Stitch cutters**
- **Stitch cutter sets**
- **Acupuncture needles**
- **Oxygen catheters**
- **Suction catheters**
- **Disinfectants**
- **Urine bags**
- **Skin markers**
- **Rectal tubes**
- **Urological catheters**
- **Sterile medical drapes**
- **Tweezers for single use**
- **Bandaging materials**
- **Bladder syringes**
- **Blood pressure monitors (aneroid)**
- **Copolymer examination gloves**

Hamburg, 11 July 2019


MEDCERT Certification Body
(Lorenz Runge)

EC-Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Germany**

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Disinfectants

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II excluding section 4

This certificate is valid until: 01 March 2021

Report No.: 2239FS16F
Process No.: QS - 2239
Certificate No.: 2239GB410160321

Hamburg, 21 March 2016



MEDCERT Certification Body
(Rainer Klatt)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EC-Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Germany**

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Medical devices as per attachment 1

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid until: 01 March 2021

Report No.: 2239FS16F
Process No.: QS - 2239
Certificate No.: 2239GB414160321

Hamburg, 21 March 2016

MEDCERT Identification No.: 0482



MEDCERT Certification Body
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Attachment 1
EC-Certificate of Conformity
QS - 2239

This attachment is valid only in connection with certificate No: 2239GB414160321

- **Blood lancets**
- **Medical electric thermometers**
- **Scalpels and scalpel blades**
- **Surgical gloves**
- **Vacuum bottles**
- **Nasal oxygen cannulas**
- **Redon systems**
- **Stitch cutters**
- **Stitch cutter sets**
- **Acupuncture needles**
- **Oxygen catheters**
- **Suction catheters**
- **Disinfectants**

Hamburg, 21 March 2016



MEDCERT Certification Body
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EC-Certificate of Conformity

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Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Germany**

has introduced, applies and maintains a Quality Assurance System **concerning the conformity of the medical devices with the metrological requirements** for the products / product categories:

- **Blood pressure monitors (aneroid)**
- **Bladder syringes**

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid until: 01 March 2021

Report No.: 2239FS16F
Process No.: QS - 2239
Certificate No.: 2239GB416160321

Hamburg, 21 March 2016



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EC-Certificate of Conformity

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Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**megro GmbH & Co. KG
Am Schornacker 30
46485 Wesel
Germany**

has introduced, applies and maintains a Quality Assurance System for the aspects of manufacture **concerned with securing and maintaining sterile conditions** for the products / product categories:

Medical devices as per attachment 1

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid until: 01 March 2021

Report No.: 2239FS16F
Process No.: QS - 2239
Certificate No.: 2239GB415160321

Hamburg, 21 March 2016



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Attachment 1
EC-Certificate of Conformity
QS - 2239

This attachment is valid only in connection with certificate No: 2239GB415160321

Medical devices
concerned with securing and maintaining sterile conditions

- **Urine bags**
- **Skin markers**
- **Infusion sets for gravity infusion**
- **Rectal tubes**
- **Urological catheters**
- **Sterile medical drapes**
- **Tweezers for single use**
- **Bandaging materials**
- **Bladder syringes**

Hamburg, 21 March 2016



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