



## EC Certificate

### Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-15-343

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

### SCHÖNN MEDIZINTECHNIK GmbH

Helena Rubinstein Straße 4-G Erkrath, Deutschland

**Products:** Medical Vacuum Supply System, AGSS Supply System, Medical Oxygen and Nitrous Oxide Supply System, Medical Air Supply System, Medical Gas Terminal Units, Oxygen Flowmeters, Vacuum Regulators, Zone Wall Units, Operating Room Control Panels, Intensive Care Units, Pendants, Bed Head Units, Medical Copper Tubes and Fittings.

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details. This certificate is valid until 04 February 2018.

**Report Number:** M.4478.01

30 June 2015, Istanbul, Turkey

Head of Notified Body

Certificate





**Enclosure of the EC Certificate:**

**Full Quality Assurance System according to  
Medical Devices Directive 93/42/EEC Annex-II Section 3  
Certificate Number: 1984-MDD-15-343**

Concerned medical devices;

**Product:** Medical Vacuum Supply System

**Product:** AGSS Supply System

**Product:** Medical Oxygen and Nitrous Oxide Supply System

**Product:** Medical Air Supply System

**Model No:** 30-551-00

**Product:** Medical Gas Terminal Units

**Product:** Oxygen Flowmeters

**Model No:** 10-130-100, 10-130-200, 10-130-300, 10-130-400

**Product:** Vacuum Regulators

**Product:** Zone Wall Units

**Product:** Operating Room Control Panels

**Product:** Intensive Care Units

**Model No:** 90-350-000, 90-351-000, 90-355-000

**Product:** Pendants

**Model No:** 90-301-102, 90-302-102, 90-303-102, 90-304-102, 90-307-102,  
90-306-250

**Product:** Bed Head Units

**Model No:** 90-320-000, 90-321-000, 90-322-000, 90-323-000, 90-324-00

**Product:** Medical Copper Tubes and Fittings

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

30 June 2015, Istanbul, Turkey

Head of Notified Body

Certificate