



# Certificate

No. Q6 016522 0013 Rev. 00

**Holder of Certificate:** **CODAN PORTUGAL**  
**Instrumentos Médicos, S.A.**  
Rua Stig Husted-Andersen, 4  
2675-492 Odivelas  
PORTUGAL

**Facility(ies):** CODAN PORTUGAL Instrumentos Médicos, S.A.  
Rua Stig Husted-Andersen, 4, 2675-492 Odivelas, PORTUGAL

**Certification Mark:**



**Scope of Certificate:** **Production and Distribution of Sterile Single-Use Medical Devices for Infusion and Transfusion Therapy as well as for Mixing and Withdraw Products**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713146861

**Valid from:** 2019-05-08

**Valid until:** 2020-09-30

**Date,** 2019-05-08

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

## Supplement to Quality System Certificate

No. SUP 016522 0014 Rev. 00

**This supplement is only valid in conjunction with the main certificate:**

**Q6 016522 0013 Rev. 00**

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The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 "Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

**Audit Report:** 713146861  
**Dated:** 2019-01-28

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

**Valid from:** 2019-05-08

Stefan Preiß

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