Supplement to Quality System Certificate

No. SUP 016522 0014 Rev. 01

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

Q6 016522 0013 Rev. 02

Certificate Holder:

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

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:

Dated:

713176630

2020-04-23

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:

2020-04-23

Christoph Dicks

Head of Certification/Notified Body