

Supplement to Quality System Certificate

No. SUP 062256 0016 Rev. 00

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

Q5 062256 0015 Rev. 01

Certificate Holder: Kawamoto Corporation

2-6-4 Tanimachi Chuoku, Osaka 540-0012 JAPAN

Facility(ies): Kawamoto Corporation

2-6-4 Tanimachi, Chuoku, Osaka, 540-0012 JAPAN

Kawamoto Corporation Osaka-Plant 3-14-20 Tadaokahigashi, Tadaokacho, Senbokugun,

Osaka, 595-0805 JAPAN

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: JN1730480_CN Dated: 2021-12-02

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: 2022-04-06

Christoph Dicks

Head of Certification/Notified Body