



Product Service

Certificate

No. Q8 021282 0015 Rev. 00

Holder of Certificate: **ALMO-Erzeugnisse
Erwin Busch GmbH**
Große Allee 84
34454 Bad Arolsen
GERMANY

Certification Mark:



Scope of Certificate: **The Provision of Design and Development services of non-sterile and sterile general non-active, non-implantable medical devices like Syringes and Oral Dispenser.**

The Provision of plastic manufacturing, packaging and ETO sterilization services of general non-active, non-implantable medical devices.

The Provision of plastic components for general non-active, non-implantable medical devices. The Provision of ETO sterilization services for medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8_021282_0015_Rev.00

Report No.: 713331173

Valid from: 2024-10-22
Valid until: 2027-10-21

Date, 2024-10-15

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **ALMO-Erzeugnisse Erwin Busch GmbH**
Große Allee 84, 34454 Bad Arolsen, GERMANY

See Scope of Certificate

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