ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q8 113865 0001 Rev. 00

Holder of Certificate: **KHTP STERILISATION SERVICES SDN BHD**
Lot 33, Jalan Hi-Tech 4
Kulim Hi-Tech Park
09090 Kulim, Kedah Darul Aman
MALAYSIA

Facility(ies): KHTP STERILISATION SERVICES SDN BHD
Lot 33, Jalan Hi-Tech 4, Kulim Hi-Tech Park, 09090 Kulim, Kedah Darul Aman, MALAYSIA

See Scope of Certificate

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Provision of Ethylene Oxide Sterilization Services Involving the Process of Sterilization of Medical Devices**

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, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 113865 0001 Rev. 00

Report No.: 5501223-721428207

Valid from: 2022-07-15
Valid until: 2025-07-14

Date, 2022-07-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

Supplement to Quality System Certificate

No. SUP 113865 0002 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q8 113865 0001 Rev. 00**

Certificate Holder:

KHTP STERILISATION SERVICES SDN BHD
Lot 33, Jalan Hi-Tech 4
Kulim Hi-Tech Park
09090 Kulim, Kedah Darul Aman
MALAYSIA

Facility(ies):

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

EN ISO 11135 : 2014 + AMD1 2019– Sterilization of health care products –
Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Audit Report: 5501223-721428207
Dated: 2022-07-14

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: 2022-07-15

Christoph Dicks
Head of Certification/Notified Body

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