

Supplement to Quality System Certificate

No. SUP 109216 0002 Rev. 02

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

Q5 109216 0001 Rev. 02

Certificate Holder:



SCHOTT POONAWALLA PRIVATE LIMITED

Survey No.606/P,606/1,2,3,608/P-1,608/2, 609/5/6/2,609/1,609/5/6,610/1 and 610/9, Coastal Highway, Village - Umarsadi Taluka - Pardi, District - Valsad Gujarat 396125 INDIA

Facility(ies):

SCHOTT POONAWALLA PRIVATE LIMITED

Survey No.606/P,606/1,2,3,608/P-1,608/2,, 609/5/6/2,609/1,609/5/6,610/1 and 610/9,, Coastal Highway, Village - Umarsadi, Taluka - Pardi, District - Valsad, Gujarat 396125, INDIA

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

EN ISO 11135-1:2014 -Sterilization of healthcare products- Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2014)

Audit Report:

201530000137

Dated:

2024-03-29

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:

2024-07-29



Christoph Dicks
Head of Certification/Notified Body