

Supplement to Quality System Certificate

No. SUP 109216 0002 Rev. 01

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

Q5 109216 0001 Rev. 01

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,Costal Highway,
Village: Umarsadi
Taluka - Pardi, District - Valsad 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,Costal Highway,
Village: Umarsadi, Taluka - Pardi, District - Valsad 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:

IND2020078

Dated:

2021-01-11

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:

2022-08-30



Christoph Dicks
Head of Certification/Notified Body