



Certificate

No. Q5 109216 0001 Rev. 02

Holder of Certificate:



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

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design & Development, Manufacture and Supply of Sterile & Non-Sterile-Cartridges / Crimped Cartridges, Prefillable syringe & Components including Plunger, Stoppers, Finger grips / Backstops.

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

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:Q5_109216_0001_Rev.02

Report No.: 201530000137
Valid from: 2024-07-29
Valid until: 2027-07-28



Date, 2024-06-11

Christoph Dicks
Head of Certification/Notified Body