



Certificate

No. Q5 110138 0001 Rev. 00

Holder of Certificate: **S.H.Pitkar Orthotools Pvt.Ltd**

EL-32, J Block, MIDC, Bhosari
Pune, Maharashtra 411026
INDIA

Facility(ies):

S.H.Pitkar Orthotools Pvt.Ltd
EL-32, J Block, MIDC, Bhosari, Pune, Maharashtra 411026, INDIA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design, development, manufacture and distribution of orthopaedic implants (bone screws & plates, spinal implants, intramedullary locking nails, pins, wires), appliances (external fixation system), instruments (drills, reamers, hammers, jigs, drill guides, wire tensioner, wrench)

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:Q5 110138 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_110138_0001_Rev_00)

Report No.: IND2020114

Valid from: 2021-08-25

Valid until: 2024-08-24

Date, 2021-08-25



Christoph Dicks

Head of Certification/Notified Body