



Certificate

No. Q5 003920 0005 Rev. 00

Holder of Certificate: **Betatex S.p.a.**
Viale Europa Zona Industriale
06083 Ospedalichio Bastia Umbra (PG)
ITALY

Certification Mark:



Scope of Certificate: Design and development, manufacturing and sales of single-use medical devices: drapes, specialistic kits and procedure packs for operating theatre and related single-use accessories, components and surgical instruments; incontinence aids, gowns and clothes for hospital use in nonwoven fabric non sterile, sterilizable and sterile.

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_003920_0005_Rev_00

Report No.: ITA1699638

Valid from: 2021-09-05
Valid until: 2024-09-04

Date, 2021-09-03



Christoph Dicks
Head of Certification/Notified Body



Product Service

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Betatex S.p.a.
Viale Europa Zona Industriale, 06083 Ospedalichio Bastia Umbra
(PG), ITALY

See scope of certificate

Betatex S.p.A.
Loc. Venella, 52044 Terontola di Cortona AR, ITALY

See scope of certificate

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