

Certificate

mdc medical device certification GmbH
certifies that

Aurosan GmbH
Frankenstraße 231
45134 Essen
Germany

with the locations listed in the attachment
for the scope

development, manufacturing and distribution of
medical devices for dental implantology and of urinary catheters
service and repair of diagnostic and therapeutic medical devices for General Medicine,
Neonatology, Occupational Health, Neuro-Otology, Obstetrics/Gynecology, Urology,
Microbiology, Pediatrics, ENT, Hearing Aid Acoustics and Medical Prevention

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-09-07
Valid until	2021-12-29
Registration no.	D1405000008
Report no.	P19-01439-185357
Stuttgart	2020-09-07



Head of Certification Body



Attachment of the certificate

No. D1405000008

date 2020-09-07

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Location	Scope
Aurosan GmbH, Essen Kleine Ruhrau 20 45279 Essen	distribution of medical devices for dental implantology and of urinary catheters
Aurosan GmbH Frankenstraße 231 45134 Essen	development, manufacturing and distribution of medical devices for dental implantology and of urinary catheters
RÖSCH Medizintechnik GmbH Buckower Chaussee 100 12277 Berlin	distribution, service and repair of diagnostic and therapeutic medical devices for General Medicine, Neonatology, Occupational Health, Neuro-Otology, Obstetrics/Gynecology, Urology, Microbiology, Pediatrics, ENT, Hearing Aid Acoustics and Medical Prevention



A handwritten signature in blue ink, consisting of several fluid, connected strokes, is positioned above a horizontal line.

Head of Certification Body