

Certificate

mdc medical device certification GmbH
certifies that

STRATEC Consumables GmbH
Sonystraße 20
5081 Anif
Austria

for the scope

**Design, Development and Production including backend processing of
plastic consumables for in-vitro diagnostic use**

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	2021-07-01
Valid until	2024-06-30
Registration no.	D4006600002
Report no.	P21-00212-197631
Stuttgart	2021-04-30



Head of Certification Body

