

Certificate

We hereby certify the company

STRATEC Consumables GmbH
Sonystraße 20
5081 Anif
Austria

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

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

An audit by mdc has proven that this quality management system meets the requirements of the following
standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-05-27
Valid until 2027-05-26

Registration No. D4006600003
Report No. P24-00253-291713

Stuttgart, 2024-05-24



Certification Body

