



CERTIFICATE



This is to certify that the company

STRATEC SE

Gewerbestraße 37
75217 Birkenfeld
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

The design and development, manufacture and distribution of automated analyzer instruments, intended for processing assays in the field of in-vitro diagnostics and life sciences
-AUS (a), BRA, CND, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

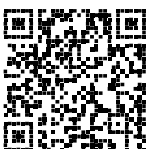
Certificate registration no.	351745 MDSAP16
Certificate unique ID	170779323
Effective date	2022-07-08
Expiry date	2024-08-09
Frankfurt am Main	2022-07-08



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.



Annex to certificate
Certificate registration No.: 351745 MDSAP16
Certificate unique ID: 170779323
Effective date: 2022-07-08

STRATEC SE

Gewerbestraße 37
75217 Birkenfeld
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Audited site

351745
STRATEC SE
Gewerbestraße 37
75217 Birkenfeld
Germany

REPs FEI No.: site scope and country-specific requirements

The design and development, manufacture and distribution of automated analyzer instruments, intended for processing assays in the field of in-vitro diagnostics and life sciences
-AUS (a), BRA, CND, USA (a,b,c,d)
REPs FEI No.: F005433

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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821