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	1000167593
Effective date	2024-08-10
Expiry date	2027-08-09
Frankfurt am Main	2024-05-17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 351745 MDSAP16
Certificate unique ID: 1000167593
Effective date: 2024-08-10

STRATEC SE

Gewerbestraße 37
75217 Birkenfeld
Germany

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

Annex to certificate
Certificate registration No.: 351745 MDSAP16
Certificate unique ID: 1000167593
Effective date: 2024-08-10

STRATEC SE

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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