



CERTIFICATE



This is to certify that the company

Girtec AG

Palmestr. 1
8583 Sulgen
Switzerland

with the organizational units/sites as listed in the annex

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

Scope of certification:

Development of respiratory technology devices, production and distribution of respiratory technology, anaesthesia technology, aspiration systems, shock wave therapy technology, devices for product preparation (sterilizers, washing machines), dosing systems for medication, dialysis technology, wound care systems and wound prevention, insufflation devices, medical gas supply and cardiology devices.

- **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.	550525 MDSAP16
Certificate unique ID	1000197214
Effective date	2025-03-08
Expiry date	2027-02-24
Frankfurt am Main	2025-03-08



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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 the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 550525 MDSAP16
Certificate unique ID: 1000197214
Effective date: 2025-03-08

Girtec AG

Palmestr. 1
8583 Sulgen
Switzerland

Audited site

550525
Girtec AG
Palmestr. 1
8583 Sulgen
Switzerland

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

Development of respiratory technology devices, production and distribution of respiratory technology, anaesthesia technology, aspiration systems, shock wave therapy technology, devices for product preparation (sterilizers, washing machines), dosing systems for medication, dialysis technology, wound care systems and wound prevention, insufflation devices, medical gas supply and cardiology devices.

- USA (a,b,c,d)

REPs FEI No.: F007397



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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 Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 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