




America

CERTIFICATE

No. QS6 101355 0005 Rev. 00

Certificate Holder: MedRx Inc
1200 Starkey Rd Suite # 105
Largo FL 33771
USA

Certification Mark: 

Scope of Certificate: Design and Development, Manufacture, Distribution and Service of Audiometric Equipment, Hearing Aid Analysers, Headphones, Patient Switch and Ear Tips for the area of Audiology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 84-931-1261

Effective Date: 2019-04-15

Expiry Date: 2022-04-14

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Date of Issue: 2019-04-16

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

MedRx Inc
1200 Starkey Rd Suite # 105, Largo FL 33771, USA

DGS Diagnostics Sp. z o. o.
ul. Zeusa 2, 72-006 Mierzyn, POLAND

DGS Diagnostics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

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DUNS No: 84-931-1261

DGS Diagnostics Sp. z o. o.

ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacture, Distribution and Service of Audiometric Equipment, Hearing Aid Analysers for the area of Audiology

DUNS No: 42-543-8180

DGS Diagnostics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

Manufacture, Distribution, Service and Calibration of Audiometric Equipment, Hearing Aid Analysers for the area of Audiology

DUNS No: 30-630-8354



(Arie Henkin)
Manager, Certification Body MHS

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