



America

CERTIFICATE

No. QS2 088915 0004 Rev. 02

Certificate Holder: **Tegra Medical**
9 Forge Park
Franklin MA 02038
USA

Certification Mark:



Scope of Certificate: **Contract Manufacturer Providing Process Engineering Solutions for Metal and Plastic Components, Assemblies and Devices Serving the Medical Device, Diagnostic and Life Sciences Industries**

Standard: **ISO 13485:2016**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **72169095**

Effective Date: **2022-05-04**

Expiry Date: **2024-04-19**

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Date of Issue: 2022-05-09

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



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No. QS2 088915 0004 Rev. 02

- Facility(ies):** **Tegra Medical**
9 Forge Parkway, Franklin MA 02038, USA
- Facility Scopes:** Contract Manufacturer Providing Process Engineering Solutions for Metal and Plastic Components, Assemblies and Devices Serving the Medical Device, Diagnostic and Life Sciences Industries
- Facility(ies):** **Tegra Medical**
8 Ledgewood Blvd., Dartmouth, MA 02747, USA
- Facility Scopes:** Contract Manufacturer Providing Process Engineering Solutions for Metal and Plastic Components, Assemblies and Devices Serving the Medical Device, Diagnostic and Life Sciences Industries
- Facility(ies):** **Tegra Medical LLC**
16 Forge Park, Franklin MA 02038, USA
- Facility Scopes:** Contract Manufacturer Providing Process Engineering Solutions for Metal and Plastic Components, Assemblies and Devices Serving the Medical Device, Diagnostic and Life Sciences Industries

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services