



Product Service

Certificate

No. Q8 106512 0001 Rev. 05

Holder of Certificate: **Variosystems AG**

Amperestraße 5
9323 Steinach
SWITZERLAND

Certification Mark:



Scope of Certificate: **The provision of component and assembly manufacturing (services) for active medical devices. The provision of Design and Development (services) for mechatronic and software for active medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8 106512 0001 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q8_106512_0001_Rev_05)

Report No.: 713380785

Valid from: 2026-03-19

Valid until: 2029-03-18

Date, 2026-03-10

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Variosystems AG**
Amperestraße 5, 9323 Steinach, SWITZERLAND

The provision of component and assembly manufacturing (services) for active medical devices. The provision of Design and Development (services) for mechatronic and software for active medical devices.

Variosystems Inc.
901 South Kimball Ave., Southlake TX 76092, USA

The provision of component and assembly manufacturing (services) for active medical devices.

Variosystems (Pvt.) Ltd.
Nelumwatta, Kotadeniyawa Road, 11538 Badalgama, SRI LANKA

The provision of component and assembly manufacturing (services) for active medical devices.

Variosystems d.o.o.
Ulica Katarine Zrinski 10, 42000 Varaždin, CROATIA

The provision of component and assembly manufacturing (services) for active medical devices.

Variosystems AG
Via San Martino 20, 6850 Mendrisio, Ticino, SWITZERLAND

The provision of component and assembly manufacturing (services) for active medical devices.

Variosystems AG
Tardisstrasse 225, 7205 Zizers, SWITZERLAND

The provision of component and assembly manufacturing (services) for active medical devices.

Variosystems AG
Gewerbstrasse 4, 9470 Buchs, SWITZERLAND

The provision of Design and Development services for mechatronic and software for active medical devices.



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Variosystems Romania S.R.L.

Strada Ungureni 103, 77118 Șanțu Florești, ROMANIA

The provision of component and assembly manufacturing (services) for active medical devices.

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