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Zentralstelle der Länder
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bei Arzneimitteln und
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Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 045508 0008 Rev. 00

Manufacturer: **SensLab Gesellschaft zur
Entwicklung und Herstellung
bioelektrochemischer Sensoren mbH**
Bautzner Straße 67
04347 Leipzig
GERMANY

Facility(ies): SensLab Gesellschaft zur Entwicklung und Herstellung
bioelektrochemischer Sensoren mbH
Bautzner Straße 67, 04347 Leipzig, GERMANY

Product Category(ies): In Vitro diagnostic for self testing

Model(s): **Lactate measuring system for self testing
Lactate Scout+, Lactate Scout 4**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

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Stefan Preiß

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