



Product Service

Certificate

No. Q5 040330 0193 Rev. 01

Holder of Certificate: **DiaMed GmbH**
Pra Rond 23
1785 Cressier FR
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and development, manufacturing and distribution of in-vitro diagnostic medical devices (products, reagents, instruments and software) for immunohaematology, haematology and immunochemistry**

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:Q5 040330 0193 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_040330_0193_Rev_01)

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Valid from: 2025-09-02
Valid until: 2027-10-30

Date, 2025-09-02

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): **DiaMed GmbH**
Pra Rond 23, 1785 Cressier FR, SWITZERLAND

Design and development, manufacturing and distribution of in-vitro diagnostic medical devices (products, reagents, instruments and software) for immunohaematology, haematology and immunochemistry

Bio-Rad Medical Diagnostics GmbH
Industriestraße 1, 63303 Dreieich, GERMANY

Design and development and manufacturing of in-vitro diagnostic medical devices (products, reagents, instruments and software) for immunohaematology, haematology and immunochemistry.

Bio-Rad Medical Diagnostics GmbH
Industriestraße 4, 63303 Dreieich, GERMANY

Manufacturing of in-vitro diagnostic medical devices (products, reagents) for immunohaematology, haematology and immunochemistry.

Bio-Rad Medical Diagnostics GmbH
Heinrich-Hertz-Str. 1, 63303 Dreieich, GERMANY

Distribution of in-vitro diagnostic medical devices (products, reagents) for immunohaematology, haematology and immunochemistry

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