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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 115293 0002 Rev. 00

Certificate Holder: **Biovica International AB**
Uppsala Science Park
Dag Hammarskjölds väg 54B
752 37 Uppsala
SWEDEN

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Reagents for Oncology based on Enzyme Activity Methods**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **USA FDA. 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 115293 0002 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006905**
Report No.: **75957501**
Effective Date: **2023-08-21**
Expiry Date: **2026-08-20**

Date of Issue: 2023-08-28

(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 115293 0002 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Biovica International AB**
Uppsala Science Park, Dag Hammarskjölds väg 54B, 752 37 Uppsala, SWEDEN

Facility Scopes: Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Reagents for Oncology based on Enzyme Activity Methods
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