MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 102395 0003 Rev. 00

Certificate Holder: **Cell Marque Corporation**
6600 Sierra College Blvd.
Rocklin CA 95677
USA

Certification Mark:

M.S.D.N:0310805269 - C.T.T.N.H.H. CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM Q.BÌNH THẠNH - T.P HỒ CHÍ MINH

Trương Thị Tố Hoa
Trưởng phòng Đăng ký,
Đối ngoại và Quản lý Chất lượng

Scope of Certificate: **Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Medical Devices and In-Vitro Diagnostic Reagents used in Clinical Research, Clinical Histology and / or Clinical Cytology to Aid in the Identification and / or Differentiation of Neoplasms and Infectious Disease Agents in Tissues**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, 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. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **02-504-8773**

Effective Date: **2020-01-03**

Expiry Date: **2023-01-02**

Date of Issue: 2020-01-06

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 102395 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

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

Facility(ies):

Cell Marque Corporation
6600 Sierra College Blvd., Rocklin CA 95677, USA

Cell Marque Corporation
Ste 400, 6630 Sierra College Blvd., Rocklin CA 95677, USA

Cell Marque Corporation
Ste 100, 6630 Sierra College Blvd, Rocklin CA 95677, USA

Date of Issue: 2020-01-06

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 102395 0003 Rev. 00

Facility Scopes:

Cell Marque Corporation
6600 Sierra College Blvd., Rocklin CA 95677, USA

Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Medical Devices and In-Vitro Diagnostic Reagents used in Clinical Research, Clinical Histology and / or Clinical Cytology to Aid in the Identification and / or Differentiation of Neoplasms and Infectious Disease Agents in Tissues
DUNS No: 02-504-8773

Cell Marque Corporation
Ste 400, 6630 Sierra College Blvd., Rocklin CA 95677, USA

Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Medical Devices and In-Vitro Diagnostic Reagents used in Clinical Research, Clinical Histology and / or Clinical Cytology to Aid in the Identification and / or Differentiation of Neoplasms and Infectious Disease Agents in Tissues
DUNS No: 02-504-8773

Cell Marque Corporation
Ste 100, 6630 Sierra College Blvd., Rocklin CA 95677, USA

Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Medical Devices and In-Vitro Diagnostic Reagents used in Clinical Research, Clinical Histology and / or Clinical Cytology to Aid in the Identification and / or Differentiation of Neoplasms and Infectious Disease Agents in Tissues
DUNS No: 02-504-8773

Date of Issue: 2020-01-06

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com