

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **20-1612-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

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 Devices Regulations – Part 1- SOR/98-282. **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.



Rovers Medical Devices B.V.
Lekstraat 10, 5347 KV Oss,
The Netherlands

DUNS number: **40-215-5084**

Additional sites covered by QM System: *N/A*

List of Products: *See Annex I*

Design, Manufacturing and Distribution of Sterile and Non-Sterile Cell Sampling Devices

The validity of this certification document can be obtained by contacting the TUV USA, Inc. office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **20-3848 RC-CA**

Current Cycle Start Date: **2020-10-23**

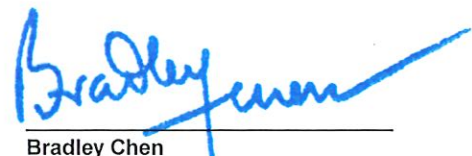
Certificate Revised Date: *N/A*

Effective Date:

2020-10-23 / ed. 1

Valid Until:

2023-10-22



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Annex I, page 1 of 2
(Annex I MUST be displayed with the main certificate)



Certificate Registration No. : 20-1612-M / ed. 1
Company Name: *Rovers Medical Devices B.V.*
Central Office Address: *Lekstraat 10, 5347 KV Oss, The Netherlands*

Products	UMDNS	GMDN
Cell Sampling Devices: Rovers® Cervex-Brush® (sterile and non-sterile)	15-018	42537
Rovers® Cervex-Brush® Combi (sterile and non-sterile)		
Rovers® EndoCervex-Brush® (sterile and non-sterile)		
Rovers® EndoCervex-Brush®-S (sterile and non-sterile)		
Rovers® Viba-Brush (sterile and non-sterile)		

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Company Name: *Rovers Medical Devices B.V.*
Central Office Address: *Lekstraat 10, 5347 KV Oss, The Netherlands*

Products	UMDNS	GMDN
Cell Sampling Devices: Rovers® Anex® Brush (sterile)	15-018	42537
Rovers® Orcellex® Brush (sterile)		
Rovers® Evalyn® Brush (sterile)		
Delphi Screener (sterile)		

---End of list---

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