C E R T I F I C A T E

Management system as per

ISO 13485:2016 (MDSAP)

The Certification Body TUV USA, Inc. hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

Rovers Medical Devices B.V.
Lekstraat 10
5347 KV Oss,
The Netherlands
[Facility ID: F004435]

with products according to annex 1

operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3 year term of validity of the certificate for 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. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009, **Canada:** Medical Devices Regulations – Part 1- SOR/98-282. **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, **United States:** 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Design, manufacturing, and distribution of sterile and non-sterile cell sampling devices

Certificate Registration No. 20-1612-M
Audit Report No. 22-4032 RC

Valid from 2023-11-22
Valid until 2026-10-22
Initial certification 2020-10-23

Recognized Auditing Organization
at TUV USA, Inc.

Salem, NH 2023-11-22 ed. 2

TUV USA, Inc is recognised under the Medical Device Single Audit Program

The validity of this certification document can be obtained by contacting the TUV USA, Inc, office.
Tel: 001-603-870-8023 (option 1), Email: medical-usa@tuv-nord.com

ANNEX 1

to Certificate Registration No. 20-1612-M
ISO 13485:2016 (MDSAP)

Rovers Medical Devices B.V.
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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)		
Rovers® Anex® Brush (sterile)		
Rovers® Orcellex® Brush (sterile)		
Rovers® Evalyn® Brush (sterile)		

End of the List

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