



DECLARATION OF CONFORMITY

We, Rovers Medical Devices B.V.,

SRN NL-MF-000001553
Role Manufacturer
Country Netherlands
Actor Rovers Medical Devices B.V.
Abbreviated name RMD

declare under our sole responsibility that the Rovers® non-sterile cell sampling devices of this declaration (See table 1) are in conformity with REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Product group : Cell Sampling Devices, **Class I NON-STERILE** products, Rule 5
 UMDNS Code : 15-018
 GMDN Code : 42537

Product Name:	Catalogue numbers ((x) pcs/bag)	Basic UDI-DI
Rovers® Cervex-Brush®	380100311 (50)	87191892463801003113V
	380100324 (25)	871918924638010032446
	491461 (25)	871918924600049146125
	70671-001 (25)	871918924607067100158
	380300324 (25)	87191892463803003244Y
Rovers® Cervex-brush® Combi	380101000 (25)	87191892463801010003G
	380101010 (50)	87191892463801010103K
	491462 (25)	871918924600049146227
	380101030 (25)	87191892463801010303R
	380301000 (25)	87191892463803010004A
Rovers® EndoCervex-Brush®	380100703 (50)	87191892463801007034J
Rovers® EndoCervex-Brush®-S	380100740 (50)	87191892463801007404Q
Rovers® Viba-Brush®	380200115 (50)	871918924638020011548

Table 1: Product group Non-Sterile Cell Sampling Devices



The conformity with the requirements outlined in Annex I, Annex II, Annex III, Article 19 and Annex IV has been assessed;

- This declaration is supported by the Quality System certification based on the harmonized standard EN-ISO 13485:2016, Quality System Certificate #: 44 221 121392 granted by TÜV NORD CERT GmbH, Certificate validity from 03.04.2020 until 02.04.2023.
- And supported by the Quality System certification ISO 13485:2016 under MDSAP for Medical Device Requirements under the following jurisdictions;

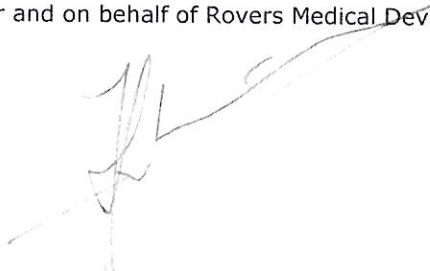
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. Brazil: RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009. Canada: Medical Devices Regulations – Part 1- SOR/98-282. Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68. USA: United States: 21 CFR 803; 21 CFR 806; 21CFR 807 – Subparts A to D; 21 CFR 820.

Quality System Certificate #: 20-1612-M granted by TUV USA, Inc., Certificate validity from 23-10-2020 until 22-10-2023.

This EU declaration of conformity is issued under the sole responsibility of Rovers Medical Devices B.V.

For and on behalf of Rovers Medical Devices B.V.

March 19th, 2021



H.J.M. Vissers,
Senior QA/RA Manager.

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