DECLARATION OF CONFORMITY

We, Rovers Medical Devices B.V.,

domiciled Lekstraat 10, 5347KV. Oss, The Netherlands hereby,

SRN : NL-MF-000001553
Role : Manufacturer
Country : The 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 Medical Device Regulation (EU) 2017/745.

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	Notis #'s
Rovers® Cervex-Brush®	380100311 (50)	871918924638010031 13V	20905
	380100324 (25)	87191892463801003244 6	20905
	491461 (25)	87191892460004914612 5	20900
	70671-001 (25)	87191892460706710015 8	20902
	380300324 (25)	871918924638030032 44Y	20905
	The Cervex-Brush® is a single-use cell sampler intended to collect simultaneous cell material from the cervical os, ectocervical and endo cervical in women.		
Rovers® Cervex-brush® Combi	380101000 (25)	871918924638010100 3G	20906
	380101010 (50)	871918924638010101 03K	20906
	491462 (25)	87191892460004914622 7	20901
	380101030 (25)	871918924638010103 03R	20906
	380301000 (25)	871918924638030100 04A	20906
	The Cervex-Brush® Combi is a single-use cell sampler intended to collect simultaneous cell material from the ectocervical, endocervical and transformation-zone in women.		
Rovers® EndoCervex-Brush®	380100703 (50)	871918924638010070 34J	20907
	The EndoCervex-Brush® is a single-use cell sampler intended to collect endocervical cells.		
Rovers® EndoCervex-Brush®-S	380100740 (50)	871918924638010074 04Q	20909
	The EndoCervex-Brush®-S is a single-use cell sampler intended to collect endocervical cells in women.		
Rovers® Viba-Brush®	380200115 (50)	87191892463802001 1548	20917
	The Viba-Brush® is a single use (self) cell-sampler device that allows easy, painless, safe and effective collection of cell material from the vagina.		

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 03.04.2023 until 02.04.2026.

- 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.

CH REP	Swiss AR Services GmbH, Industry Strasse 47, CH-6300 Zug, Switzerland
UK Responsible Person	Qarad UK Ltd., 8 Northumberland Ave, Westminster, London WC2N 5BY, England, United Kingdom

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. April 18th, 2023

L. Vissers,
QA/RA Manager, PRRC.

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