



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)	87191892463801003113V	20905
	380100324 (25)	871918924638010032446	20905
	491461 (25)	871918924600049146125	20900
	70671-001 (25)	871918924607067100158	20902
	380300324 (25)	87191892463803003244Y	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)	87191892463801010003G	20906
	380101010 (50)	87191892463801010103K	20906
	491462 (25)	871918924600049146227	20901
	380101030 (25)	87191892463801010303R	20906
	380301000 (25)	87191892463803010004A	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)	87191892463801007034J	20907
	The EndoCervex-Brush® is a single-use cell sampler intended to collect endocervical cells.		
Rovers® EndoCervex-Brush®-S	380100740 (50)	87191892463801007404Q	20909
	The EndoCervex-Brush®-S is a single-use cell sampler intended to collect endocervical cells in women.		
Rovers® Viba-Brush®	380200115 (50)	871918924638020011548	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 03.04.2020 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.



Swiss AR Services GmbH, Industry Strasse 47, CH-6300 Zug, Switzerland

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.

September 7th, 2022

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