



## 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® sterile cell sampling devices of this declaration (See table 1) are in conformity with the European Medical Device Directive, 93/42/EEC, 14 June 1993 as amended by Medical Device Directive, 2007/47/EEC, 5 September 2007(MDD) and its relevant transportation into national laws of the member states into we place the devices.

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

Product Name:	Catalogue numbers ((x) pcs/bag)	Basic UDI-DI
Rovers® Anex® Brush	380090331 <sup>2)</sup>	87191892463800903316R
	380390331 <sup>3)</sup>	87191892463803903317Y
	491430 <sup>3)</sup>	8719189246000491430ZP
Rovers® Cervex-Brush®	380100331 <sup>1)</sup>	871918924638010033143
	490722 <sup>1)</sup>	871918924600049072223
	380100431 <sup>2)</sup>	871918924638010043148
	380300331 <sup>3)</sup>	87191892463803003314V
Rovers® Cervex-Brush® Combi	380101031 <sup>1)</sup>	87191892463801010313T
	490723 <sup>1)</sup>	871918924600049072325
	380102031 <sup>2)</sup>	871918924638010203142
	380301031 <sup>3)</sup>	87191892463803010314M
Rovers® EndoCervex-Brush®	380100731 <sup>1)</sup>	87191892463801007314P
	490724 <sup>1)</sup>	871918924600049072427
	380300731 <sup>3)</sup>	87191892463803007315H
Rovers® EndoCervex-Brush®-S	380100745 <sup>1)</sup>	871918924638010074552
	490725 <sup>1)</sup>	871918924600049072529
	380300745 <sup>3)</sup>	87191892463803007455U
Rovers® Orcellex® Brush	380800331 <sup>1)</sup>	87191892463808003316W
	380380331 <sup>3)</sup>	87191892463803803317M
	491429 <sup>3)</sup>	871918924600049142929
Rovers® Viba-Brush®	380200131 <sup>1)</sup>	871918924638020013146
	380200331 <sup>3)</sup>	87191892463802003314G
	380320331 <sup>4)</sup>	87191892463803203315K
Rovers® Evalyn® Brush	380500131	87191892463805001315D
	380500150	87191892463805001505H

Table 1: Product group Cell Sampling Devices

<sup>1)</sup> Blue handle, <sup>2)</sup> Green handle, <sup>3)</sup> Remover Tube (RT), <sup>4)</sup> Fuchsia handle

The conformity with the requirements of the Directive has been assessed following the procedure outlined in Annex II of the MDD:

- Notified Body #: 0044, TÜV NORD CERT GmbH, Langemarckstr. 20, 45141 Essen, Germany EC Certificate (MDD Annex II, without (4)) #: 44 232 121392, Certificate validity from 03.04.2020 until 26.05.2024;
- 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.

An application for the above mentioned products is not lodged to any other Notified Body than mentioned in this declaration.

On behalf of Rovers Medical Devices B.V.;

April 6<sup>th</sup>, 2020



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

Doc. ID: 2021096LED

