Rovers®
medical devices

# 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) | 871918924638010031 13V |
| | 380100324 (25) | 87191892463801003244 6 |
| | 491461 (25) | 87191892460004914612 5 |
| | 70671-001 (25) | 87191892460706710015 8 |
| | 380300324 (25) | 87191892463803003244Y |
| Rovers® Cervex-brush® Combi | 380101000 (25) | 87191892463801010003G |
| | 380101010 (50) | 87191892463801010103K |
| | 491462 (25) | 87191892460004914622 7 |
| | 380101030 (25) | 87191892463801010303R |
| | 380301000 (25) | 87191892463803010004A |
| Rovers® EndoCervex-Brush® | 380100703 (50) | 87191892463801007034J |
| Rovers® EndoCervex-Brush®-S | 380100740 (50) | 87191892463801007404Q |
| Rovers® Viba-Brush® | 380200115 (50) | 87191892463802001154 8 |

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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