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[2)]	871918924638009033l6R
	380390331[3)]	871918924638039033l7Y
	491430[3)]	871918924600049143OZP
Rovers® Cervex-Brush®	380100331[1)]	871918924638010033143
	490722[1)]	871918924600049072223
	380100431[2)]	871918924638010043148
	380300331[3)]	871918924638030033l4V
Rovers® Cervex-Brush® Combi	380101031[1)]	871918924638010103l3T
	490723[1)]	871918924600049072325
	380102031[2)]	871918924638010203142
	380301031[3)]	871918924638030103l4M
Rovers® EndoCervex-Brush®	380100731[1)]	871918924638010073l4P
	490724[1)]	871918924600049072427
	380300731[3)]	871918924638030073l5H
Rovers® EndoCervex-Brush®-S	380100745[1)]	871918924638010074552
	490725[1)]	871918924600049072529
	380300745[3)]	871918924638030074l5U
Rovers® Orcellex® Brush	380800331[1)]	871918924638080033l6W
	380380331[3)]	871918924638038033l7M
	491429[3)]	871918924600049142929
Rovers® Viba-Brush®	380200131[1)]	871918924638020013146
	380200331[3)]	871918924638020033l4G
	380320331[4)]	871918924638032033l5K
Rovers® Evalyn® Brush	380500131	871918924638050013l5D
	380500150	871918924638050015l5H

Table 1: Product group Cell Sampling Devices
[1)] Blue handle, [2)] Green handle, [3)] Remover Tube (RT), [4)] 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 6th, 2020

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

Doc. ID: 2021096LED