Bayer Oy Pansiontie 47 FI-20210 Turku Finland	**Certificate of Analysis**	Page: 1 of 3 Date: 2021-11-05

Material: 86996790	MIRENA 1X1 EVO EG

Batch:	TU03769	Country: Egypt
Date of manufacture:	2021-05-21	
Expiry date:	2024-05-31	

From material:	83033836	MIRENA EVO STERILIZED EXT.		
Batch:	TU033RP		Insp. instruction:	P.5.2.01 - 5
Inspection lot:	040002410160		Specification:	P.5.1.01 - 5

Inspection	Acceptance criterion	UoM	Result
Appearance	must comply		complies
Formulation	Intrauterine system		Intrauterine system
Surface property	free from visible impurities		free from visible impurities
Colour of hormone sleeve	white to nearly white		nearly white
Identity (TLC)	must comply		complies
Sum of all impurities (TLC)	max. 2.0	%	0.7
Ethylene oxide	max. 5	ppm	2
Ethylene chlorohydrin	max. 10	ppm	1
Breaking force	min. 12	N	28 23 24 24 25 26 25 24 24 25
Breaking force, 10 s.u. no.o.single val.	min.9 s.u. with min.12 N		complies
Breaking force, 10 s.u. no.o.single val.	10 s.u. with min.9 N		complies
Breaking force, 20 s.u. no.o.single val.	min.19 s.u. with min.12 N		---

Bayer Oy Pansiontie 47 FI-20210 Turku Finland	**Certificate of Analysis**	Page: 2 of 3 Date: 2021-11-05

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Inspection lot:	040002410160		Specification:	P.5.1.01 - 5

Inspection	Acceptance criterion	UoM	Result
Assay of system	47 - 58	mg	53 53 53 53 53 54 52 52 53 51
Uniformity of content, 10 s.u.	min.9 s.u. in 47-58 mg		complies
Uniformity of content, 10 s.u.	10 s.u. in 45-60 mg		complies
Uniformity of content, 20 s.u.	min.19 s.u. in 47-58 mg		---
Uniformity of content, 20 s.u.	20 s.u. in 45-60 mg		---
Release rate during 24 h, 6 s.u.	15 - 30	µg	23 22 22 22 22 22
Sterility	sterile		sterile

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full conformation with the GMP requirements of the local Regulatory Authority and with the local Marketing Authorization specifications of the destination countries (s) / product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in conformation with GMP.
This document is signed by Qualified Person.

Bayer Oy Pansiontie 47 FI-20210 Turku Finland	**Certificate of Analysis**	Page: 3 of 3 Date: 2021-11-05
Material: 86996790	MIRENA 1X1 EVO EG	
Batch: TU03769 Date of manufacture: 2021-05-21 Expiry date: 2024-05-31		Country: Egypt
Comment:	N/A	

Batch release electronically signed: Heini Lahti (GLXMH)

Date/time: 2021-10-15 09:34:32 a.m. EET (UTC + 2 hours)
Inspection lot: 040002444251