Miudella
copper intrauterine system

MIUDELLA® REMS
Healthcare Setting Enrollment Form

For real-time processing, certification in the MIUDELLA REMS can be completed online at www.MIUDELLAREMS.com.
For more information, please call the MIUDELLA REMS at 1-855-337-0772.

INSTRUCTIONS

To become a certified healthcare setting in the REMS and dispense MIUDELLA, have the authorized representative:

1. Review the **Healthcare Setting Guide**.
2. Enroll in the REMS by completing and submitting this **Healthcare Setting Enrollment Form** to the REMS by fax to 1-855-781-2610.

NOTE: Healthcare settings must have one or more healthcare providers certified to dispense MIUDELLA for insertion affiliated with the address before the healthcare setting can be certified.

COMPLETE ALL REQUIRED FIELDS TO HELP EXPEDITE THE ENROLLMENT PROCESS

HEALTHCARE SETTING INFORMATION (*denotes required field)		
*Healthcare Setting Name:		
Note: Use the identifier(s) associated with the address where the product will be shipped. Incorrect information could delay orders.		
*Healthcare Setting NPI Number:		
Healthcare Setting HIN Number:	Healthcare Setting DEA Number:	
*Address Line 1:		
Address Line 2:		
*City:	*State:	*Zip Code:
*Office Phone:		*Fax:
Type of Healthcare Setting: ☐ Private, Group ☐ Private, Individual ☐ Private, Hospital/Healthcare System ☐ Government Healthcare System ☐ Community Clinic ☐ Other: _____		

AUTHORIZED REPRESENTATIVE INFORMATION (*denotes required field)			
*First Name:	M.I.:	*Last Name:	
*Credentials (check all that apply): ☐ MD/DO ☐ PA/NP/CNM ☐ Nurse (e.g., RN/LVN/LPN) ☐ Practice Manager ☐ Office Staff ☐ Office Administration ☐ Other: _____			Title:
*City:		*State:	*Zip Code:
*Mobile Phone:	*Fax:	*Email:	
*Preferred Method of Contact: ☐ Office Phone ☐ Email ☐ Mobile Phone ☐ Text Message ☐ Fax			

CERTIFIED HEALTHCARE PROVIDERS (HCPs) AFFILIATED WITH THIS HEALTHCARE SETTING (at least one required)		
*First Name:	*Last Name:	*NPI Number:
First Name:	Last Name:	NPI Number:
First Name:	Last Name:	NPI Number:
First Name:	Last Name:	NPI Number:

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MIUDELLA® REMS
Healthcare Setting Enrollment Form (Continued)

REVIEW THE AGREEMENTS BELOW

As the healthcare setting's Authorized Representative, to become certified to dispense MIUDELLA, I must:

- Carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting.
- Review the **Healthcare Setting Guide**.
- Enroll in the REMS by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing MIUDELLA on the REMS requirements.
- Establish processes and procedures:
  - To verify that all healthcare providers who dispense MIUDELLA for insertion are certified and are affiliated with the healthcare setting are certified.
  - To maintain records of healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with the healthcare setting.
  - To monitor healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with the healthcare setting to identify providers with a two-year period of inactivity to ensure these healthcare providers maintain certification in the REMS before dispensing MIUDELLA for insertion.

Before dispensing, healthcare setting staff must:

- Verify that the healthcare provider who is inserting MIUDELLA at the healthcare setting is certified through the processes and procedures established as a requirement of the REMS.

At all times, my healthcare setting must:

- Monitor healthcare providers who are certified to dispense MIUDELLA for insertion to identify providers with a two-year period of inactivity to ensure these healthcare providers maintain certification in the REMS before dispensing MIUDELLA for insertion through the processes and procedures established as a requirement of the REMS.
- Not distribute, transfer, loan, or sell MIUDELLA except to certified pharmacies and healthcare settings.
- Maintain records that all processes and procedures are in place and being followed.
- Maintain records of healthcare providers who are certified to dispense MIUDELLA for insertion and are affiliated with my healthcare setting.
- Comply with audits carried out by Sebela Women's Health Inc. or a third party acting on behalf of Sebela Women's Health Inc. to ensure that REMS processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS.

PROVIDE SIGNATURE BELOW

By signing below, I acknowledge the above agreements and my obligations as Authorized Representative of a MIUDELLA Healthcare Setting to comply with REMS requirements, and I understand my personally identifiable information provided above will be shared with Sebela Women's Health Inc., its agents, contractors, and affiliates and entered into a Healthcare Setting database for the REMS. I agree that I may be contacted in the future by mail, email, fax, and/or phone concerning MIUDELLA, the REMS, and other MIUDELLA programs and services.

***Authorized Representative Signature:** _____ ***Date (MM/DD/YYYY):** _____

Report adverse events to Organon LLC at 1-844-674-3200 or to the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.