

Procedure Team Qualification Status Form

HEPZATO KIT™
(melphalan) for Injection/
Hepatic Delivery System (HDS)

PHONE: 1-833-632-0457
EMAIL: coordinator@HEPZATOKITREMS.com
WEB: www.HEPZATOKITREMS.com

INSTRUCTIONS

HEPZATO KIT is only available through the HEPZATO KIT Risk Evaluation and Mitigation Strategy (REMS) to mitigate the risks of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events.

Healthcare settings that dispense HEPZATO KIT must be certified and percutaneous hepatic perfusion (PHP) procedure team members who perform PHP procedures with HEPZATO KIT must be qualified by meeting the following requirements:

- Having a PHP procedure team with expertise in interventional radiology, anesthesiology, and perfusion as described in the Instructions For Use
- Reviewing the Prescribing Information, Instructions for Use, **Program Overview**, **Didactic Modules**, and completing of the Preceptorship training and Proctorship training provided by Delcath Systems, Inc.
- Performing one procedure in the first six months following completion of training, a second procedure in the next six months, and at least two procedures annually thereafter

The above qualifications must be confirmed to obtain authorization prior to dispensing each HEPZATO KIT for administration by completing and submitting this form to the REMS Coordinating Center via e-mail at coordinator@HEPZATOKITREMS.com or online at www.HEPZATOKITREMS.com.

Authorized Representative (all fields are required)

First Name:	Last Name:
Email:	Phone:
Department:	

Healthcare Setting Information (all fields are required)

Healthcare Setting Name:		
Address Line 1:		
Address Line 2:		
City:	State:	Zip Code:

Anticipated Percutaneous Hepatic Perfusion Procedure Date

Anticipated Procedure Date:

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Specialist Role: Interventional Radiology (all fields are required)		
First Name:	Last Name:	
National Provider Identifier (NPI) #:		
Healthcare Setting Name:		
Date Prescribing Information including Instructions for Use, REMS Program Overview , and Didactic Modules Reviewed:	Date:	Trainer Name:
Date of Preceptorship Training Provided by Delcath:	Date:	Trainer Name:
Date of Proctorship Training Provided by Delcath:	Date:	Trainer Name:
Dates of Two (2) Prior Procedures Performed with HEPZATO KIT:		

Specialist Role: Anesthesiology (all fields are required)		
First Name:	Last Name:	
National Provider Identifier (NPI) #:		
Healthcare Setting Name:		
Date Prescribing Information including Instructions for Use, REMS Program Overview , and Didactic Modules Reviewed:	Date:	Trainer Name:
Date of Preceptorship Training Provided by Delcath:	Date:	Trainer Name:
Date of Proctorship Training Provided by Delcath:	Date:	Trainer Name:
Dates of Two (2) Prior Procedures Performed with HEPZATO KIT:		

Specialist Role: Perfusion (all fields are required)		
First Name:	Last Name:	
National Provider Identifier (NPI) #:		
Healthcare Setting Name:		
Date Prescribing Information including Instructions for Use, REMS Program Overview , and Didactic Modules Reviewed:	Date:	Trainer Name:
Date of Preceptorship Training Provided by Delcath:	Date:	Trainer Name:
Date of Proctorship Training Provided by Delcath:	Date:	Trainer Name:
Dates of Two (2) Prior Procedures Performed with HEPZATO KIT:		