EN For use with the Equil Ambulatory Insulin Infusion Pump and Equil Insulin Infusion Set.

Insulin Infusion Pump Reservoir

MTM-3 # MTM-R10

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EU REP

CMC Medical Devices & Drugs S.L
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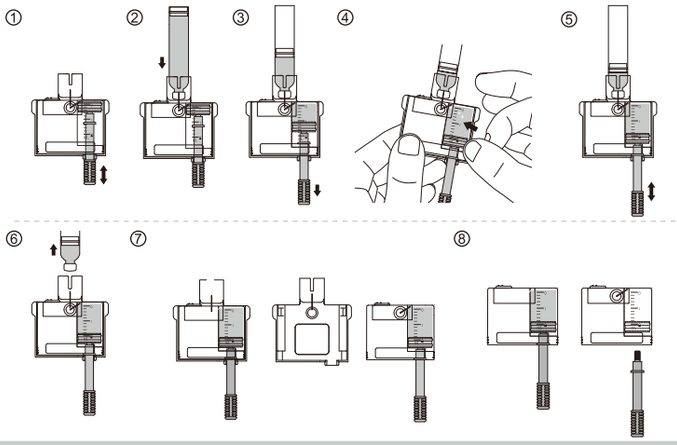
Málaga-Spain

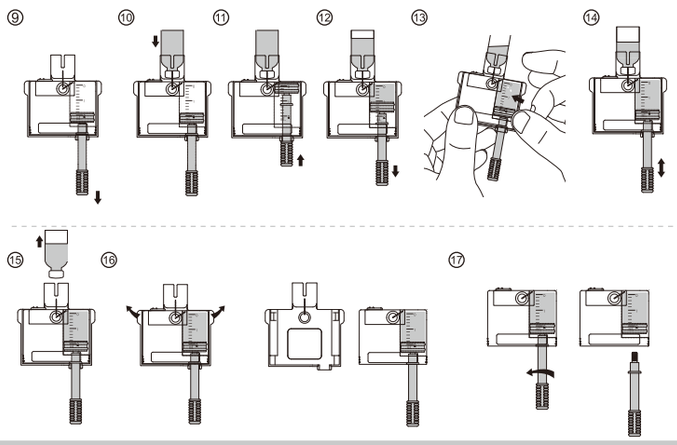
1001-PMTL-427.V02
Effective Date:2025-12-23

MicroTech Medical

CE 0197

equil





EN English

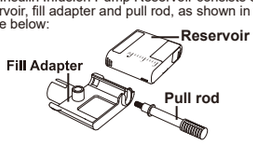
Product Name: Insulin Infusion Pump Reservoir
MTM-3(The fill adapter for 3 mL insulin cartridge)
MTM-R10(The fill adapter for 10 mL insulin vial)
Shelf Life: 3 years

1. Intended purpose

The insulin infusion pump reservoir is intended for the subcutaneous delivery of insulin when using with insulin infusion set and ambulatory insulin infusion pump.

2. Components

The Insulin Infusion Pump Reservoir consists of a reservoir, fill adapter and pull rod, as shown in the figure below:



The total capacity of the reservoir is 2.0ml, which is equal to 200 units of U-100 insulin.

3. Intended Patient

Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

4. Intended user

From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.

Requirement for professional users:

- Graduate from medical school or graduate with medical related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:

- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your leaning needs. Your healthcare provider can help you to coordinate and set up appropriate training. For pediatric patients, 'lay person'refers to caregiver, parent, or legal guardian.

5. Indications

① Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
② Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
③ Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

6. Expected use environment

Hospital setting and Home setting.

7. Contraindication

① Diabetic patients unwilling to perform insulin pump treatment.
② Patients who do not want to or do not have access to self-monitoring of blood glucose levels.
③ Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia).
④ Allergies, including insulin allergies and severe skin allergies.
⑤ People who are unconscious or disoriented.
⑥ People who are intellectually impaired and unable to understand or master the instructions for use.
⑦ People with severe visual or hearing impairments.
⑧ Elderly diabetics living alone.
⑨ Children with diabetes who are too young to take care of themselves.
⑩ The pump system has not been evaluated in:
  • Pregnant woman
  • Children below 3 years
⑪ Diabetic patients who do not require insulin therapy.
⑫ Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.
⑬ Patients with any of the following conditions should not use this product:
  • Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
  • White blood cell count lower than 4.0 × 10^9/L (weakened immunity, higher risk of infection);
  • Platelet count lower than 90 × 10^9/L (reduced clotting ability, higher risk of bleeding).
⑭ Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.
⑮ Hyperglycemic patients with severe circulatory disorders.
⑯ Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.
⑰ Patients and family members lacking relevant knowledge and still unable to use the device correctly after training.Diabetic patients unwilling to perform insulin pump treatment.

8. Application

This Insulin Infusion Pump Reservoir is compatible only with MictoTech Ambulatory Insulin Infusion Pump and Insulin Infusion Set. The compatible devices and models are as follows:

- MTM-3 and MTM-R10

Compatible device	
Name	**Model**
Ambulatory Insulin Infusion Pump	MTM-1
Insulin Infusion Set	HRN-S-60 software cannula with MTM-4 pump base
	HRN-S-90 software cannula with MTM-4 pump base

9. Usage

The fill adapter for 3 ml insulin cartridge:

① Remove the new reservoir from the packaging.
② Use the pull rod to pull the piston to the full position inside the reservoir, then push it completely to the empty position. Repeat this three times ending with the piston in the empty position (Figure 1).
③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 2).
④ With the insulin vial on top, insert the needle into the vial, slowly pull the pull rod and draw insulin into the reservoir (Figure 3).
⑤ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 4).
⑥ Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again (Figure 5).
⑦ Remove the insulin vial from the fill adapter (Figure 6).
⑧ Pull the two release tabs away from the reservoir to release the fill adapter (Figure 7).
⑨ Remove the pull rod by unscrewing it counterclockwise (Figure 8).

The fill adapter for 10 ml insulin vial:

① Remove the new reservoir from the packaging.
② Use the pull rod to pull the piston to the full position inside the reservoir (Figure 9).
③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 10).
④ Insert the needle into the vial and inject the air, injecting air makes it easier to withdraw insulin from the vial (Figure 11).
⑤ Slowly pull the pull rod downwards in the direction of the arrow to fill the reservoir with insulin (Figure 12).
⑥ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 13).
⑦ Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again and there are no any air bubbles (Figure 14).
⑧ Remove the insulin vial from the fill adapter (Figure 15).
⑨ Release the reservoir from the fill adapter (Figure 16).
⑩ Remove the pull rod by unscrewing it counterclockwise(Figure 17).

10. Precautions

① Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. Microtech Medical is not liable for any related legal obligations arising from misuse.
② Use Ambulatory Insulin Infusion Pump, pump battery, and Insulin Infusion Set manufactured by MicroTech or bearing the Equil brand identifier. The use of non-compatible components may compromise product safety, leading to insufficient or excessive insulin delivery and subsequent glycemic risks.
③ Regular blood glucose (BG) monitoring is crucial for verifying the effectiveness of insulin delivery.
④ The Fill Adapter contains a needle. Handle with care when drawing insulin. Keep the Fill Adapter out of reach of children.
⑤ This product has been sterilized by EO (Ethylene Oxide) and packaged in a sterile barrier. Do not use if the package is damaged.
⑥ This product can only be used to administer U-100 insulin.

11. Warnings

① Use only components that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
② Before proceeding, ensure you are fully familiar with the reservoir operation procedures.
③ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
④ The insulin reservoir must be replaced every 72 hours after activation.

12. Potential Clinical Benefits

- Improved management of A1C, GMI and TIR for tighter glycemic control.
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

13. Potential Risks

① Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis
② Infusion site problems
  • Pruritus (Skin redness), Swelling and other skin allergies
③ Hyperglycemia or hypoglycaemia
④ Hardware defects
  • Adhesion issues, difficulty peeling off the device, cannula deformation, etc.
⑤ Failure to follow the instructions may lead to risks of hyperglycemia or hypoglycemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycemia can potentially lead to death.

14. Electronic Manual

You can visit our website at any time to browse or download the latest electronic manual of this product: https://microtechmd.com/support/download/83/148

15. Notes

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Insulin should be at room temperature before filling the Reservoir.

Use immediately after filling. Do not store insulin in the Reservoir when the Reservoir is not in use.

This product should be used under the guidance of doctors or other healthcare professionals. It can be used in a home or hospital environment after proper training. If you are a new user, you should prepare your first reservoir with professional help.

Please read this insert carefully before use and follow the directions. Read the Ambulatory Insulin Infusion Pump and Insulin Infusion Set user guides carefully as well.

16. Sterilization Information

Sterilization method: ethylene oxide sterilization

17. Operating Condition

- Temperature range: 5°C to 40°C (41°F to 104°F)
- Relative humidity range: 10% to 93%
- Atmospheric pressure range: 70kPa-106kPa

18. Storage Condition

- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

19. Symbol list

Do not re-use	
Caution	
Use-by date	
Lot number	LOT
Single sterile barrier system with protective packaging outside using ethylene oxide	STERILE EO
Single sterile barrier system. Sterilized using ethylene oxide	STERILE EO
Sterilized using ethylene oxide	STERILE EO
Consult instructions for use	
Do not use if package is damaged	
Manufacture date	
Manufacturer	
CE Mark	CE 0197
Authorised Representative in the European Community	EU REP
Medical device	MD
Model number	#
Importer	
Unique device identifier	UDI
Operating temperature limitation	5°C 40°C
Operating humidity limitation	10% 93%
Operating atmospheric pressure limitation	70kPa 106kPa
Storage temperature limitation	-40°C 55°C
Storage humidity limitation	5% 95%
Storage atmospheric pressure limitation	50kPa 106kPa
Do not resterilize	

EN For use with the Equil Ambulatory Insulin Infusion Pump and Equil Insulin Infusion Set.

Insulin Infusion Pump Reservoir

[ ] MTM-3 [#] MTM-R10

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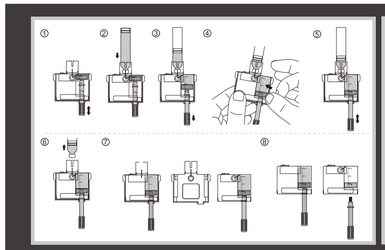

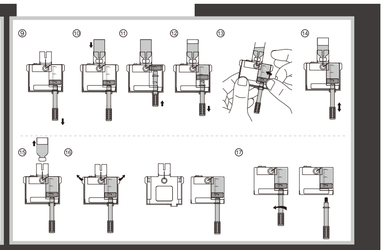

EN English

Product Name: Insulin Infusion Pump Reservoir
[ ]MTM-3(The fill adapter for 3 mL insulin cartridge)
[#]MTM-R10(The fill adapter for 10 mL insulin vial)
Shelf Life: 3 years

1. Intended purpose
The insulin infusion pump reservoir is intended for the subcutaneous delivery of insulin when using with insulin infusion set and ambulatory insulin infusion pump.

2. Components
The Insulin Infusion Pump Reservoir consists of a reservoir, fill adapter and pull rod, as shown in the figure below:

The total capacity of the reservoir is 2.0ml, which is equal to 200 units of U-100 insulin.

3. Intended Patient
Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

4. Intended user
From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.
Requirement for professional users:
- Graduate from medical school or graduate with medical related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:
- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note
Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your learning needs. Your healthcare provider can help you to coordinate and set up appropriate training. For pediatric patients, lay person refers to caregiver, parent, or legal guardian.

5. Indications
① Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
② Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
③ Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

6. Expected use environment
Hospital setting and Home setting.

7. Contraindication
① Diabetic patients unwilling to perform insulin pump treatment.
② Patients who do not want to or do not have access to self-monitoring of blood glucose levels.
③ Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia).
④ Allergies, including insulin allergies and severe skin allergies.
⑤ People who are unconscious or disoriented.
⑥ People who are intellectually impaired and unable to understand or master the instructions for use.
⑦ People with severe visual or hearing impairments.
⑧ Elderly diabetics living alone.
⑨ Children with diabetes who are too young to take care of themselves.
⑩ The pump system has not been evaluated in:
- Pregnant woman
- Children below 3 years

⑪ Diabetic patients who do not require insulin therapy.
⑫ Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.
⑬ Patients with any of the following conditions should not use this product:
- Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
- White blood cell count lower than 4.0 × 10⁹/L (weakened immunity, higher risk of infection);
- Platelet count lower than 90 × 10⁹/L (reduced clotting ability, higher risk of bleeding).

⑭ Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.
⑮ Hyperglycemic patients with severe circulatory disorders.
⑯ Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.
⑰ Patients and family members lacking relevant knowledge and still unable to use the device correctly after training.Diabetic patients unwilling to perform insulin pump treatment.

8. Application
This Insulin Infusion Pump Reservoir is compatible only with MicroTech Ambulatory Insulin Infusion Pump and Insulin Infusion Set. The compatible devices and models are as follows:
- MTM-3 and MTM-R10

Compatible device	
Name	Model
Ambulatory Insulin Infusion Pump	MTM-1
Insulin Infusion Set	HRN-S-60 software cannula with MTM-4 pump base
	HRN-S-90 software cannula with MTM-4 pump base

9. Usage
The fill adapter for 3 ml insulin cartridge:
① Remove the new reservoir from the packaging.
② Use the pull rod to pull the piston to the full position inside the reservoir, then push it completely to the empty position. Repeat this three times ending with the piston in the empty position (Figure 1).
③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 2).
④ With the insulin vial on top, insert the needle into the vial, slowly pull the pull rod and draw insulin into the reservoir (Figure 3).
⑤ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 4).
⑥ Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again (Figure 5).
⑦ Remove the insulin vial from the fill adapter (Figure 6).
⑧ Pull the two release tabs away from the reservoir to release the fill adapter (Figure 7).
⑨ Remove the pull rod by unscrewing it counterclockwise (Figure 8).

The fill adapter for 10 ml insulin vial:
① Remove the new reservoir from the packaging.
② Use the pull rod to pull the piston to the full position inside the reservoir (Figure 9).
③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 10).
④ Insert the needle into the vial and inject the air, injecting air makes it easier to withdraw insulin from the vial (Figure 11).
⑤ Slowly pull the pull rod downwards in the direction of the arrow to fill the reservoir with insulin (Figure 12).
⑥ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 13).
⑦ Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again and there are no any air bubbles (Figure 14).
⑧ Remove the insulin vial from the fill adapter (Figure 15).
⑨ Release the reservoir from the fill adapter (Figure 16).
⑩ Remove the pull rod by unscrewing it counterclockwise(Figure 17).

10. Precautions
① Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. MicroTech Medical is not liable for any related legal obligations arising from misuse.
② Use Ambulatory Insulin Infusion Pump, pump battery, and Insulin Infusion Set manufactured by MicroTech or bearing the Equil brand identifier. The use of non-compatible components may compromise product safety, leading to insufficient or excessive insulin delivery and subsequent glycemic risks.
③ Regular blood glucose (BG) monitoring is crucial for verifying the effectiveness of insulin delivery.
④ The Fill Adapter contains a needle. Handle with care when drawing insulin. Keep the Fill Adapter out of reach of children.
⑤ This product has been sterilized by EO (Ethylene Oxide) and packaged in a sterile barrier. Do not use if the package is damaged.
⑥ This product can only be used to administer U-100 insulin.

11. Warnings
① Use only components that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
② Before proceeding, ensure you are fully familiar with the reservoir operation procedures.
③ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
④ The insulin reservoir must be replaced every 72 hours after activation.

12. Potential Clinical Benefits
- Improved management of A1C, GMI and TIR for tighter glycemic control.
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

13. Potential Risks
① Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis
② Infusion site problems
- Pruritus (Skin redness), Swelling and other skin allergies

③ Hyperglycaemia or hypoglycaemia
④ Hardware defects
- Adhesion issues, difficulty peeling off the device, cannula deformation, etc.

⑤ Failure to follow the instructions may lead to risks of hyperglycaemia or hypoglycaemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycaemia can potentially lead to death.

14. Electronic Manual
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15. Notes
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Insulin should be at room temperature before filling the Reservoir.
Use immediately after filling. Do not store insulin in the Reservoir when the Reservoir is not in use.
This product should be used under the guidance of doctors or other healthcare professionals. It can be used in a home or hospital environment after proper training. If you are a new user, you should prepare your first reservoir with professional help.
Please read this insert carefully before use and follow the directions. Read the Ambulatory Insulin Infusion Pump and Insulin Infusion Set user guides carefully as well.

16. Sterilization Information
Sterilization method: ethylene oxide sterilization

17. Operating Condition
- Temperature range: 5°C to 40°C (41°F to 104°F)
- Relative humidity range: 10% to 93%
- Atmospheric pressure range: 70kPa-106kPa

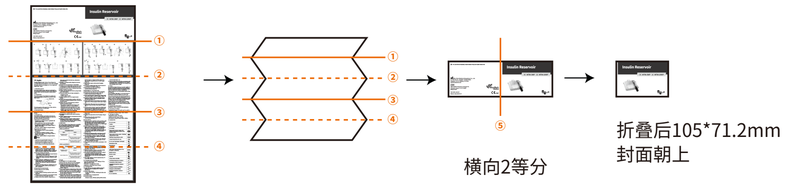
18. Storage Condition
- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

19. Symbol list

Do not re-use	
Caution	
Use-by date	
Lot number	LOT
Single sterile barrier system with protective packaging outside using ethylene oxide	
Single sterile barrier system. Sterilized using ethylene oxide	
Sterilized using ethylene oxide	STERILE EO
Consult instructions for use	
Do not use if package is damaged	
Manufacture date	
Manufacturer	
CE Mark	CE 0197
Authorised Representative in the European Community	EC REP
Medical device	MD
Model number	#
Importer	
Unique device identifier	UDI
Operating temperature limitation	5°C 40°C 41°F 104°F
Operating humidity limitation	10% 93%
Operating atmospheric pressure limitation	70kPa 106kPa
Storage temperature limitation	-40°C 50°C -40°F 122°F
Storage humidity limitation	5% 95%
Storage atmospheric pressure limitation	50kPa 106kPa
Do not resterilize	

折叠方式

外折线
内折线



纵向5等分

横向2等分

折叠后105*71.2mm
封面朝上

微泰医疗® MICROTECH MEDICAL

本图纸应与说明，产品状况，产品结构设计图及有关图纸协调使用，发现任何差异请立即通知设计师.

图档中所有尺寸比例为1:1.
公差: L(长)*(宽): +1/-1mm,H(高): ±1mm

项目信息	
名称	MTM-3&MTM-R10储药器说明书（MDR）
图纸号	
物料号	1001-PMTL-427
版本号	V02
版本变更描述	更改章节3/4/5内容
发放范围	生产（ ）采购（ √ ）计划（ √ ）其他:

切刀 压线 开槽 半穿 粘合

备注 无印刷

尺寸: 210*356mm	设计审核		日期
印刷颜色: 黑白	设计		
材质: 70g轻涂纸	审核		
特种工艺:			
备注:	批准		
	生效日期		