provide whether there are product items for export that fall under the applied categories of manufacturing processes.

6　医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律関係手数料令において定める区分適合性調査手数料を機構の口座に払い込んだことを証する書類の写しを裏面に貼付すること。

Affix a copy of the receipt for the remittance of investigation fee to the bank account of the agency, as provided in the Government Order on the fees related to the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices.

様式第七十五の六の四（第百三十七条の三十四の五関係）
Form No.75－6－4 (related to Article 137－34－5)
第　　号

基　準　確　認　証
Certificate of GCTP compliance of a manufacturing site

住所（法人にあつては、主たる事務所の所在地）
Address (In the case of a corporation, location of the head office)
氏名（法人にあつては、名称及び代表者の氏名）
Name (In the case of a corporation, its name and the name of its representative)

製造所の名称 Name of the manufacturing site	
製造所の所在地 Location of the manufacturing site	
製造業の許可区分又は再生医療等製品外国製造業者の認定区分 License category of the manufacturer, or accreditation category of the foreign regenerative medicine product manufacturer	
製造業の許可番号又は再生医療等製品外国製造業者の認定番号 Number of the license for the manufacturer, or of the accreditation for the foreign regenerative medicine product manufacturer	
製造工程の区分 Categories of the manufacturing processes	

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第23条の25の２において準用する同法第14条の２第５項の規定により、同法第23条の25第２項第４号の規定に基づき定められた再生医療等製品の製造管理及び品質管理の基準に関する省令に定める基準に適合していることを証明する。

Pursuant to Article 14-2, Paragraph 5 of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices as applied mutatis mutandis under Article 23-25-2 of same Act, it is hereby certified that the above manufacturing site complies with the standards prescribed in the Ministerial Ordinance on the Standards of Manufacturing Control and Quality Control for Regenerative Medicine Products (GCTP Ministerial Ordinance), which were established based on Article 23-25, Paragraph 2, item 4 of the Act.

年　月　日
Year　Month　Day

独立行政法人医薬品医療機器総合機構理事長　印
Chief Executive of the Pharmaceuticals and Medical Devices Agency

有効期間　年　月　日から
Valid Period　From　Year　Month　Day
年　月　日まで
Until Year　Month　Day