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

Confirmation certificate of standard conformity

住所(法人にあつては、主たる事務所の所在地)

Address(Location of the head office in case of a corporation)

氏名(法人にあつては、名称及び代表者の氏名)

Name(Name and name of its representative in case of a corporation)

製造所の名称 Name of the manufacturing establishment	
製造所の所在地 Location of the manufacturing establishment	
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, cellular therapy and gene therapy products 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, cellular therapy and gene therapy products manufacturer	
製造工程の区分 Types of the manufacturing activities	

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の規定により、同法第23条の25第2項第4号に規定する基準に適合していることを証明する。

Pursuant to Article 23―25―2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, it is certificated that the above manufacturing establishment is confirmed of conformity to the standard under 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