様式第六十三の七（第百十四条の十六関係）
Form No.63—7 (related Article 114—16)

| 収入印紙<br>revenue stamp |
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医療機器<br>体外診断用医薬品 外国製造業者　登録更新申請書

Application for the registration renewal of the foreign medical device in vitro diagnostic manufacturer

| | | |
|---|---|---|
| 登録番号及び年月日<br>Number and date of the registration | | |
| 製造所の名称<br>Name of the manufacturing establishment | | |
| 製造所の所在地<br>Location of the manufacturing establishment | | |
| 製造所の責任者<br>The person responsible for the manufacturing establishment | 氏名<br>Name | |
| | 住所<br>Address | |
| 申請者（法人にあつては、その業務を行う役員を含む。）の欠格条項<br>Applicant's disqualifications (including those of the executives engaged in the services in case of a corporation) | (1) 法第75条の４第１項の規定により認定を取り消されたこと<br>History of having license being canceled pursuant to the provision of Article 75—4, Paragraph 1 | |
| | (2) 法第75条の５第１項の規定により登録を取り消されたこと<br>History of having license being canceled pursuant to the provision of Article 75—5, Paragraph 1 | |
| | (3) 禁錮以上の刑に処せられたこと<br>History of a court sentence of imprisonment or a severer punishment | |
| | (4) 薬事に関する法令で政令で定めるもの又はこれに基づく処分に違反したこと<br>Violation of Japanese laws and regulations related to pharmaceutical affairs or measures taken in accordance with these laws and regulations | |
| 備考<br>Remarks | | |

様式第六十三の七を次のように改める。