NMPA Notice about Using Chinese Description in Name of the Registration Applicant and the Recording Applicant for Imported Medical Devices (2017 No.131)

According to *Regulations for the Supervision and Administration of Medical Devices, Provisions for Medical Device Registration, Provisions for In-vitro Diagnostic Reagent Registration and Provisions for Instructions and Labels of Medical Devices* and so on regulations and provisions, medical devices that are applying for being marketed in China, shall use Chinese description in the registration applicant name. In order to implement the relevant requirements further, meet the needs of the public better, and accept the social supervision, currently, the notice of the relevant matters that using Chinese description in the registration applicant name is shown as below (hereinafter the registration applicant, the registrant and the recording applicant of the imported medical device are called by a joint name as "enterprise"):

I. The using principle of Chinese

(1) The Chinese enterprise name shall use simplified Chinese characters. The Chinese shall be translated by the enterprise itself according to the character translation principle.

(2) The Chinese enterprise name shall correspond to the original name, its content shall not be added or deleted.

The same enterprise shall use the same Chinese enterprise name.

(3) Chinese enterprise name shall not contain content and words that are detrimental to the state or the public interest, that are likely to lead the public to be deceived or misunderstood, as well as that are forbidden from other laws, regulations and provisions.

Chinese name should not be changed if the original name was unchanged. If the Chinese name must be changed according to law and regulation, the registration administrative matters change or the recording information change shall be conducted.

II. Relevant procedures and the submission documents requirements

For the registrant or recording applicant of imported medical device that has been

Hangzhou REACH Technology Group Co., Ltd.
Address：11/F., Building 1，Dongguan Hi-Tech Park，288 Qiuyi Road，Binjiang District，Hangzhou 310052, China
Tel: +86 571 8720 6555 | Fax: +86 571 8720 6533 | Email: md@cirs-group.com

registered or recorded, the Chinese enterprise name can be added by conducting the registration administrative matters change or the recording information change.

When conducting the above change application, the enterprise shall submit a statement about the Chinese enterprise name. The statement shall include the expression that the Chinese enterprise name conforms to the requirements of this notice, and that the enterprise will take the corresponding responsibility; the Chinese enterprise name in this statement shall be consistent with the Chinese description that is filled in the application form and the recording form, and the requirement for signature and seal in this statement is the same as the other submission documents.

For the situation of the same enterprise name, if the statement about the Chinese enterprise name is also the same, then the original document of the statement can be submitted only once. The copies of the statement can be submitted for the other submission projects, and the agent shall indicate the source of the original document and promise that the copies are consistent with the original one; the copies of the statement shall be signed and sealed by the agent, and it is not necessary to be signed and sealed by the enterprise.

III. Requirement about time

(1) Since the release date of this notice, for the registrant or recording applicant of imported medical device that has been registered or recorded, the Chinese enterprise name can be added by conducting the registration administrative matters change or the recording information change.

(2) Since July 1, 2018, when the enterprise is applying registration, registration extension, approval matters change and recording application, the Chinese enterprise name shall be filled in the corresponding columns of the application form and recording form.

(3) For the imported Class I medical device that has been recorded, if the Chinese enterprise name is not registered, the enterprise shall change the recording information to add the Chinese enterprise name before December 31, 2018.

Since January 1, 2019, for all the imported Class I medical devices that are manufactured after January 1, 2019, the enterprise name in IFU and label shall include Chinese description, and shall be consistent with the corresponding Chinese description in the recording information or the recording information after change.

(4)For the imported Class II and Class III medical devices that have been registered,

Hangzhou REACH Technology Group Co., Ltd.
Address：11/F., Building 1，Dongguan Hi-Tech Park，288 Qiuyi Road，Binjiang District，Hangzhou 310052, China
Tel: +86 571 8720 6555 | Fax: +86 571 8720 6533 | Email: md@cirs-group.com

for the situation of the same enterprise name, the enterprise shall conduct at least one medical device registration certificate or registration change document containing Chinese enterprise name before December 31, 2018; for the other medical device registration certificates that are within the valid date, it is OK that the registration administrative matters change is not conducted separately to add Chinese enterprise name which can be conducted until registration extension or other registration change application. The enterprise can print IFUs and labels of relevant medical devices according to the Chinese enterprise name in the conducted document.

Since January 1, 2019, for all the imported Class II and Class III medical devices that are manufactured after January 1, 2019, the enterprise name in the instructions and label shall include Chinese description, and the Chinese description shall be consistent with the corresponding Chinese description in this product (or the other product of the same enterprise name) registration certificate (or registration change document).

IV. Other matters

Where a dispute arises due to the Chinese name of enterprise, it shall be handled in accordance with the provisions of the relevant laws and regulations.

Hereby it is the notice.

National Medical Products Administration
Oct. 31 2017

Hangzhou REACH Technology Group Co., Ltd.
Address：11/F., Building 1，Dongguan Hi-Tech Park，288 Qiuyi Road，Binjiang District，Hangzhou 310052, China
Tel: +86 571 8720 6555 | Fax: +86 571 8720 6533 | Email: md@cirs-group.com